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U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PATIENT-FOCUSED DRUG DEVELOPMENT PUBLIC MEETING FOR
OPIOID USE DISORDER (OUD)

10903 New Hampshire Avenue Room,
Silver Spring, MD 20993

Tuesday, April 17, 2018

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P R O C E E D I N G S

WELCOME

DR. EGGERS: -- and get started in a few minutes. I do notice that the best (technical difficulty) the planning team, who have worked very hard to put this meeting together. We have Pujita Vaidya, Graham Thompson, Meghana Chalasani, Shanon Woodward, Leila Lackey, Blake Bannister and Arianna Hughes (phonetic).

And so, please, if there's anything you need, let us know. If we have a name tag, we can help you out throughout the day.

We have a full agenda for this day -- can everyone hear me? If anyone can't hear me, please raise your hand? Okay. We have a full agenda for the day. Can I go through the slides?

SPEAKER: Yes.

DR. EGGERS: It works? Okay. After Theresa says some opening remarks, we'll have a bit of background. But our background is brief so that we can get to what the real purpose of the discussion today, is to listen to individuals with opioid use disorder as

1 well as family members and advocates.

2 So we will have two discussion topics. One
3 will focus on health effects of opioid use disorder.
4 And then we'll have a lunch. And then we'll come back
5 and have a topic on treatment approaches.

6 There is time set aside for what we call open
7 public comment later this afternoon. So while the
8 primary purpose of our discussion throughout the day is
9 to hear from individuals, families and advocates about
10 the topics that we have on the table today, we do
11 recognize that there may be others who want to provide
12 a comment or that you in the room may have a comment on
13 a different topic that you'd like to provide.

14 So if you want to participate in that open
15 public comment, there's a registration sign up form at
16 our registration table. Participation is first come,
17 first serve. And we'll close the registration at the
18 end of the break. The time allotted for each speaker
19 will be two minutes for that.

20 Okay. Lunch is an important topic. Our --
21 one of the patient advocacy groups, Addiction Policy
22 Forum, has kindly offered lunch for people who are not

1 federal, so for people who are individuals, family
2 members and others. There is -- so I believe they'll
3 have that setup in the hallway.

4 There's also a kiosk at the -- behind this
5 room, where you can preorder lunch for purchase. And
6 we suggest do preorder that and -- at a break or during
7 the discussion sometime find a time to go out and do
8 that if you would like to buy lunch.

9 Okay. We ask you to please silence your
10 phones. This meeting is being audio recorded. So we
11 are streaming a live audio recording of the meeting,
12 and that will have the presentation slides.

13 So for you in the webcast, if you're
14 participating, your participation is extremely
15 important. We value your input. We will have every
16 chance for you to participate. You can't see in the
17 room, but I am looking out at a room that is packed
18 with people here to share their experiences. So just
19 know that even if you can't see.

20 The audio recording and the slides along with
21 the meeting transcript and a summary report will be
22 made publicly available after the meeting.

1 And because of the sensitive nature of this
2 meeting topic and the importance of gathering candid,
3 meaningful input from individuals who have come forward
4 courageously to speak about living with opioid use
5 disorder, no other audio recording, video recording or
6 photography will be allowed at this patient-focused
7 drug development meetings, that means cell phones as
8 well. So please keep your cameras quiet today.

9 We ask for your cooperation and strongly
10 request that you respect the privacy of all
11 individuals. If we see anyone recording or taking
12 photos, we will ask you to stop. And if participants
13 do not comply with this request, we will need to stop
14 the meeting. So very much ask for your respect of the
15 people who have courageously attended this meeting.

16 With that, I would like to turn it to Theresa
17 for some opening remarks.

18 OPENING REMARKS

19 DR. MULLIN: Thank you, Sara. And again, good
20 morning and welcome to this meeting. We are very, very
21 happy to have so many individuals and family members
22 and advocates here in the room with us today and we

1 know that many more are joining us remotely on our
2 webcast. And we thank you very much for making the
3 time to come here today and to share with us and help
4 us understand better kind of what you're experiencing
5 and that we can learn and do better by knowing that
6 directly.

7 And we're also very happy to have you join us
8 if you're here from other stakeholder groups, if you're
9 here from industry and you want to understand what
10 patients are experiencing directly.

11 We want to learn more about what the impact of
12 opioid use disorder is for you on your life, you know,
13 what experiences you've had, the challenges you had
14 accessing treatments, your experience with treatment.
15 We understand that opioid use disorder is a very
16 serious condition with physical, emotional and social
17 impacts, that this is a big unmet need for patients.

18 And we are responsible in our work for
19 weighing the benefits and risks of drugs that companies
20 want to market to patients, and so our getting a better
21 understanding from you of what it's like to live with
22 this condition will help us in doing that kind of

1 assessment and helping us figure how to encourage the
2 best and most effective drug development in this area
3 to help treat people who are experiencing opioid use
4 disorder.

5 I also want to thank and acknowledge that we
6 have a lot of representatives, as I said, from
7 industry, other government partners. I especially want
8 to thank our NIDA colleagues for their great help in
9 making this meeting so well attended. Their outreach
10 and planning with us are going to ensure our success
11 today in trying to hear as much we can from as many of
12 you as we can. And the other partners and others who
13 have come here today to hear what experiences people
14 have had.

15 You know, FDA plays a critical role, but we're
16 not the only player in drug development. And so it's
17 important that we see this high level of interest that
18 we have here today in the room.

19 And I'm going to just go over a few slides
20 that we have here. You hear us using this term
21 patient-focused drug development. I'm just going to
22 spend a minute to talk about what do we mean by that,

1 okay.

2 Well, part of FDA's mission -- we regulate a
3 lot of things, that includes drugs, and part of that
4 job is for us to ensure that a drug that a company
5 wants to market is safe and effective for the use that
6 the company wants to put it out there. And so how do
7 we do that?

8 Well, we take -- we are very systematic in how
9 we look at these drugs and we need to make sure that
10 the benefits outweigh the risk. So we look at: how bad
11 is the condition that people are experiencing? Are
12 there other drugs available that are really taking care
13 of it, are they meeting their needs? How does this
14 drug -- what benefits does it offer? What are the
15 risks? Could we manage the risks somehow so the
16 benefit outweighs the risk? You know, that's what we
17 have to look at.

18 And what we find is that people who have the
19 condition are really, like, uniquely positioned to tell
20 us what it's like to live with disease, how bad is it,
21 how well do the drugs that are available work. So they
22 really help to understand those first two areas of

1 unmet need and severity of the condition. More than
2 the literature or doctors treating the patients,
3 patients directly can tell you things nobody else can
4 say.

5 So that's really what we understand better
6 now. And we've been trying to systematically collect
7 this kind of information from people who have different
8 diseases and we're learning a lot every time we do
9 this. And we've been calling it patient-focused drug
10 development.

11 Here's a list -- so as you can see, over the
12 past five years we've been trying to ask questions like
13 this from people with a variety of different diseases
14 which don't have good treatments today. And, you know,
15 people are suffering and they can tell us what it's
16 like in ways that help us be better about making that
17 assessment process and give better advice to companies
18 who are trying to develop drugs to treat those
19 conditions.

20 And so what we've been learning is people who
21 have the condition are experts in what it's like to
22 live with the condition. This is an industry -- like,

1 the drug industry and medical product industry, you
2 know, they consult with experts all the time, right?
3 But what we realize now is patients and individuals who
4 are living with the condition, they're experts.

5 So hearing from them we'll also hear what's
6 not being captured in those development programs, what
7 are we not looking at that we should be because those
8 people are experiencing these things.

9 And that's really -- we've learned a lot.
10 We've learned sometimes with a progressive condition
11 people would just like to get a good treatment which
12 will stop the condition from progressing any further.
13 In some cases that a relevant kind of a benefit that
14 they would like to have.

15 We also understand hearing from people lots of
16 time people want to participate and help however they
17 can. You know, there are limits to how much people who
18 have a condition can help, but they want to help as
19 much as they can.

20 So you're helping us enormously today by being
21 here in this meeting and being on this webcast because
22 you're going to help us better understand, and we're

1 going to make better and wiser decisions as a result.

2 So thank you again for joining us here today.

3 And just one more thing I'll mention is that,
4 you know, one of the things we've been looking at as
5 we've been trying to figure out what can we do to help
6 with people who are living with opioid use disorder is
7 also people have asked, "Well, how can you help more
8 with people who are living with chronic pain?" And so
9 this is another condition.

10 So in mid-July -- on July 9th we're now --
11 we're going to plan a meeting and we'll have more
12 information about it in the future. But that meeting
13 is going to focus on obtaining the perspectives of
14 people who are living with chronic pain and how is that
15 like for the -- what's that life like for them and what
16 is their experience with using drugs that are available
17 to treat chronic pain and how much more can be done
18 there.

19 So that's a similar kind of an engagement, but
20 with people who have chronic pain. And we're planning
21 for the future.

22 And with that, I just want to thank you again

1 for being here today. We're very much looking forward
2 to hearing what you're going to be able to tell us.
3 Thank you. And I'm going to turn it over now to
4 Maryam.

5 BACKGROUND ON OPIOID USE DISORDER AND TREATMENT

6 DR. AFSHAR: Good morning, everyone. Thank
7 you for being here. I am Maryam Afshar. I'm a medical
8 reviewer in the Division of -- better? -- in the
9 Division of Anesthesia, Analgesia, and Addiction
10 Products.

11 Given the diversity of understanding of the
12 opioid use disorders, I'm going to provide a brief
13 overview of the diagnosis, the impact of the disease
14 and currently available treatment options.

15 The slides you will see contain more
16 information than what we can cover in 10 minutes, but
17 they will be available on the FDA website for your
18 reference.

19 I would like to first go over some general
20 definitions and then talk about the definition of
21 opioid use disorder. Opioids are a class of drugs that
22 include heroin, opioid pain medication and synthetic

1 opioids such as Fentanyl.

2 Drug abuse is using a drug not as it was
3 prescribed or a substance in order to experience
4 psychological or physical effects. Tolerance is
5 needing to use more of a substance to get the desired
6 effect or experiencing a weaker effect when using the
7 same amount.

8 Withdrawal is experiencing psychological signs
9 such as irritability or physical signs such as cramps
10 or flu-like symptoms when not using a drug or using a
11 drug to avoid symptoms of withdrawal.

12 Dependence can be physical or psychological.
13 By physical dependence, we mean that if the drug is
14 decreased or stopped the individual will experience
15 withdrawal symptoms.

16 Physiological dependence is when the
17 individual has lost control over drug use or
18 experiences psychological distress if not able to use.
19 This corresponds to the familiar term addiction.

20 The currently used medical term is opioid use
21 disorder. Over the years, some of the terms that we
22 have been using have changed.

1 The Diagnostic and Substance -- and
2 Statistical Manual of Mental Health Disorder, or DSM-
3 IV, that was published in 1994 had opioid use disorder
4 categorized under two groups, opioid abuse and opioid
5 dependence.

6 The criteria for opioid abuse was one or more
7 symptoms of social problems due to opioid use or risky
8 use. The criteria for opioid dependence was three or
9 more symptoms including tolerance and/or withdrawal
10 symptoms.

11 Almost 20 years later, according to DSM-V,
12 opioid use disorder is now a single diagnosis with
13 different severities based on the number of symptoms
14 that are present. The signs are categorized into four
15 groups: loss of control, risky use, social problems and
16 drug effects.

17 Examples for loss of control are using more
18 than intended; spending a lot of time obtaining, using
19 or recovering from the effects of the drug; a strong
20 urge to use; repeated attempts to stop or cut down.

21 Risky use is using opioids when it is -- it
22 can be physically dangerous to use or continuing to use

1 despite experiencing physical or psychological
2 problems.

3 Symptoms of social impairment are like not
4 being able to take care of responsibilities at work,
5 school or home because of opioid use; using opioid
6 despite problems in relations; and not attending to
7 social or recreational activities because of opioid
8 use.

9 Drug effects are tolerance and withdrawal,
10 which we just talked about.

11 Opioid use disorder can be diagnosed when two
12 of 11 symptoms are present in a 12 month period.

13 Mild opioid use disorder can be diagnosed with
14 two to three symptoms. But it's important to note that
15 if those two symptoms are withdrawal and tolerance,
16 that doesn't qualify for a diagnosis if the individual
17 is taking opioid pain medication as directed.

18 Patients who are on pain medication can
19 develop tolerance, and if the medication is stopped,
20 they can experience withdrawal symptoms. But that does
21 not mean that they have opioid use disorder.

22 Moderate to severe opioid use disorder

1 corresponds roughly to what we think of as opioid
2 dependence or addiction and can benefit from medication
3 treatment.

4 Based on a 2016 national survey on drug use
5 and health, almost 12 million individuals had opioid
6 misuse and over 2 million people were diagnosed with
7 opioid use disorder. As you can see, different surveys
8 use different terms such as misuse, but the bottom line
9 is that lots of people are affected by opioid use
10 disorder.

11 This is a multifaceted problem affecting many
12 aspects of the individuals' lives, including medical
13 and psychological problems, social and financial
14 problems, even overdose and premature death.

15 Treatment is categorized in two main groups,
16 behavioral and medication treatment. This is not an
17 exhaustive list of behavioral treatments, but some
18 include cognitive behavioral therapy and peer support
19 groups.

20 The currently available medication treatments
21 are categorized based on the mechanism of action and
22 includes agonist-antagonist and partial agonist.

1 Methadone is an agonist, meaning it activates the
2 opioid receptors. It has been available since the
3 early 1970s through federally certified opioid
4 treatment programs or OTPs.

5 Individuals in OTP will have counseling and
6 regular urine drug screens and initially must show up
7 daily to receive their dose.

8 Methadone comes in different forms, liquid,
9 powder, diskette and tablet. The tablet form is mainly
10 used in pain management. Like any other medication,
11 there are side effects with methadone. It can cause
12 cardiac arrhythmia. It can also cause drug-drug
13 interactions with other medications. If used with
14 alcohol and benzodiazepine, there is a high risk of
15 respiratory depression and there's also a high risk of
16 overdose when the treatment is stopped.

17 Now, Trazodone is an antagonist, meaning it
18 blocks the opioid receptors. The extended release form
19 is a monthly intramuscular injection that can be given
20 by the patient's healthcare provider, which can improve
21 access.

22 Before starting the injection, the individual

1 must be opioid free 7 to 14 days depending on the type
2 of the opioid that they have been using. Otherwise, it
3 can cause significant withdrawal symptoms.

4 Now, Trazodone also can cause injection site
5 reaction and there is a risk of overdose after stopping
6 the treatment because of loss of tolerance.

7 Buprenorphine is a partial agonist, meaning it
8 activates opioid receptors, but it does so to a certain
9 limit. It is prescribed by healthcare providers who
10 receive special training in the office space to improve
11 access. The oral form has been available since 2002.
12 It comes as tablet and film and is absorbed through the
13 lining of the mouth.

14 A six month implant was approved in 2016 and
15 most recently a monthly injection was approved in 2017.
16 There is risk of overdose after stopping the treatment
17 and also if it's used with alcohol and/or
18 benzodiazepines.

19 We know medication treatment reduces relapse,
20 improves retention and treatment and decreases drug
21 use; whilst stopping treatment increases the risk of
22 overdose. With treatment, some patients will stop drug

1 use completely and some will use less.

2 Opioid use disorder is not simply the use of
3 opioid, but also functional and/or clinical problems
4 due to opioid use. Even though opioid use is
5 characterized by problems due to opioid use, the
6 outcome of treatment has been assessed by looking at
7 the drug use behavior and not the problems and
8 consequences.

9 Because drug use behavior is not a direct
10 measure of how the individual is doing clinically,
11 meaning how they are feeling or functioning, it is
12 considered a surrogate endpoint.

13 One thing we are here to understand is: what
14 are the ways individuals decide whether a treatment is
15 working for them, so we can use that in understanding
16 whether or not a new treatment is working.

17 What brings individuals into treatment? What
18 do individuals, families and clinicians consider
19 treatment success? How do we determine if treatment is
20 successful? Answers to these questions will help us
21 better assess treatment options from a regulatory
22 perspective. We're looking forward to your comments.

1 Thank you.

2 (Applause)

3 THE ROAD FROM PFDD MEETINGS TO CLINICAL

4 TRIAL ENDPOINTS

5 DR. PAPADOPOLOUS: Good morning again. I'm
6 Elektra Papadopoulos and I led the Clinical Outcome
7 Assessment Staff here in CDER. Our staff serves as
8 consultants to each of the therapeutic area review
9 divisions on their clinical outcome assessments,
10 including patient questionnaires to show clinical
11 benefit in drug development.

12 So where do we go from our patient-focused
13 drug development meetings? What do we do with this
14 wealth of very important information that we obtain
15 during these meetings? And I hope to be able to answer
16 some of these questions in the next few slides.

17 So patient-focused drug development meetings
18 are really important opportunity for us to hear from
19 the patients in their own words what symptoms and
20 impacts matter to them most, what they value in
21 treatment and also what amount of change in these
22 impacts would be meaningful in their daily lives.

1 Drug companies can also benefit from the
2 information that we obtain when they're going about
3 selecting what to measure in their drug developments
4 programs, as well as the FDA, where we can actually
5 confirm whether the outcome assessments that we use
6 truly capture -- truly and faithfully capture the
7 patient's priorities.

8 Now, importantly, these meetings are a
9 starting point for selecting and developing patient
10 questionnaires and other types of clinical outcome
11 assessments that we use in clinical trials to show
12 benefits of drugs. We strongly recommend that there be
13 further input from patients in the form of qualitative
14 research, and this includes in-depth patient interviews
15 and focus groups, really using rigorous scientific
16 methods.

17 Now, what is a clinical study endpoint? The
18 term endpoint refers to how a specific outcome will be
19 measured and analyzed in a clinical study. So, for
20 example, an endpoint might be a change in a symptom
21 score using a specific questionnaire, say, at six weeks
22 compared with baseline.

1 And so this is really important to understand
2 when we're trying to assess clinical benefit. So
3 anytime you read a scientific publication or you're
4 trying to understand the benefit in drug labeling, this
5 is important to understand.

6 Now, we're going to hear a lot of very
7 important concerns that you have expressed at this
8 meeting, and I wanted to say that not everything that
9 is important will lend itself to measurement as a
10 clinical endpoint in our trials.

11 So some things that might come out of this
12 meeting could be extremely important, say, as an
13 example, the impact of health on patient's finance --
14 extremely important, but not really able to show change
15 and really demonstrate a drug effect within the context
16 of a clinical trial.

17 So here at FDA we have to uphold our rules and
18 regulations and our laws, and within our regulations,
19 are the requirement that our study endpoints need to be
20 well-defined and reliable. And so what do we mean by
21 this?

22 Essentially, what we mean is that we have

1 evidence that the assessment is measuring the right
2 thing, which we call the concept, in the right way in a
3 defined population of patients and that the score can
4 accurately and reliably quantify changes that can be
5 interpreted as a clear benefit to patients. So the
6 tool needs to be able to detect change.

7 It's important to know that a lot of
8 questionnaires that we might fill out in our doctor's
9 offices may or may not be appropriate for use in
10 clinical trials, and so we need to evaluate those
11 through the specific lens of clinical trial endpoints
12 and what is really fit for purpose. It's a specific
13 purpose.

14 So, you know, I wanted to say also that
15 endpoint development can be a lengthy and expensive
16 process, and I think this really provides an important
17 opportunity for patient groups and stakeholders to come
18 together and support this process outside the context
19 of specific drug development programs so that at the
20 end of the day we can have tools that are publicly
21 available and can be used across drug development more
22 broadly.

1 So some key takeaways. The outcome of the
2 patient-focused drug development meetings will really
3 support and guide FDA risk/benefit assessments and drug
4 reviews by helping us to understand what symptoms and
5 impacts are important to patients and what they value
6 in treatment.

7 The information from patients and caregivers
8 ultimately will help us to determine what to measure to
9 provide evidence of clinical benefit, how best to
10 measure the important symptoms and impacts and how much
11 change in those impacts is meaningful to patients.

12 So in closing, many stakeholders, including
13 drug developers, researchers, clinicians, patient
14 stakeholders can play an important role in developing
15 clinical outcome assessments, including things like
16 patient questionnaires, and there are multiple pathways
17 by which these stakeholders can engage with the FDA.
18 My final slide will show some weblinks alluding to some
19 of these pathways.

20 And finally, patient-focused drug development
21 meetings are the starting point for developing patient-
22 focused outcome measures and endpoints.

1 And with that, thank you very much for your
2 attention.

3 (Applause)

4 OVERVIEW OF DISCUSSION FORMAT

5 DR. EGGERS: Okay, I'm back. Again, Sara
6 Eggers. I hope that those background presentations
7 gave you a sense. If you're new to this area of what
8 FDA does and what drug development is, then I hope we
9 gave you a little bit of background on that and
10 especially some of the key terms and words we'll be
11 using today. So thank you very much for that.

12 I'm now going to kickoff what is the main
13 feature of today's discussion. And I'm going to also -
14 - before saying that, you know, feel free to at any
15 point get up, stretch your legs. If you're meaning to
16 pre-purchase lunch from the kiosk, especially if you're
17 a federal worker and you need to do that, please do so.

18 The restrooms -- I don't think I mentioned
19 this earlier -- they're located behind this building
20 and then off -- in a hallway to the right you'll find
21 the restrooms there.

22 But please, this is an open -- as much as we

1 can make, a federal agency -- be welcoming, we're
2 trying to, so get up and walk around please. Thanks.

3 Okay. We've been talking about this. There
4 are two main topics we want to cover today. I know
5 there's a lot of words on these slides. But the first
6 topic that will be in the morning is really what's it
7 like to live with opioid use disorder and in particular
8 the health effects and the daily impacts, how it
9 affects -- how opioid use disorder affects day to day
10 life, life on the best days and the worst days and how
11 it has changed over time and what worries you most.

12 Then when we come back after lunch in the
13 afternoon it's really on current approaches to
14 treatment of opioid use disorder; your experiences and
15 your perspectives on that; what you would like to see
16 in an ideal treatment; if future treatments could be
17 better, how could they be better.

18 And what factors would you consider if you
19 would ever consider participating in a clinical trial.
20 Clinical trials are very important to drug development
21 and so we would like to know your thinking on those as
22 well.

1 So here's how it works. For each of these two
2 discussions, we're going to kickoff our discussion with
3 comments from a panel of individuals with OUD. And I'm
4 going to ask Andrew and Amanda to come up at this
5 point.

6 We have two other participants who are
7 participating on the phone. We are going to try to do
8 as much as we can going to the people on the webcast
9 and we're also using the phone as much as we can today.

10 So the purpose of the panelist is just to give
11 a story, an experience with opioid use disorder that
12 will help us kickoff a discussion with all of you who
13 identify as individuals with OUD or opioid use disorder
14 or opioid addiction, family and advocates.

15 Okay. And so it's -- I'll be coming out in
16 the front with a microphone and we're going to have my
17 colleagues have microphones and they will come to you.
18 So if it's -- if you have something to say, raise your
19 hand. We are going to try to get to as many people in
20 the room as we can.

21 There's a couple of things that help us. One
22 is if you stay -- whatever topic we're talking about,

1 if we're talking about symptoms or if we're talking
2 about daily impact, to try to think about what that
3 topic is and stay as close to that topic and try to
4 keep your points to just maybe one or two things so
5 that we can go on to as many people who want to speak
6 as possible.

7 When speaking you may remain anonymous. I
8 mean, you don't have to give us your names. You may
9 state your names if you want. But we don't care what
10 your name is. We care what your experience is. And so
11 that's what's important. The same if you're on the
12 webcast or if you're calling in on the phone.

13 Okay. Now, you'll see these funny little
14 disks on your tables. This is to give us a chance to
15 do something we call polling questions. And you can --
16 we encourage you to participate if you're an individual
17 or a family member. They really aid our discussion,
18 because we can't get -- can't -- no one can speak on
19 everything and so you have a chance to raise your hand
20 in some ways by answering polling questions. So you'll
21 use these clickers.

22 And can everyone click their clicker and just

1 see that it buzzes? You should feel a little buzz.
2 All buzzing? If no one -- if something doesn't buzz,
3 raise your hand and we'll come with a new clicker. I
4 hear that their battery life is getting to about the
5 point where we need batteries on some.

6 Okay. So we're going to ask for individual or
7 family members only please. And web participants,
8 there's a chance for you to use your computer to answer
9 these questions too. Web participants please type in.
10 You aren't here to be in person to lend your voice, but
11 we want to hear your comments on the web. Don't worry
12 about us being overwhelmed by comments. We can handle
13 it. We'll try to summarize them as much as possible.

14 We will occasionally, as time permits, go to
15 the phones to give you another opportunity. Again,
16 please if you're participating on the phone, keep it to
17 one or two things that are on the topic we're
18 discussing.

19 Okay. You can send us your comments too. We
20 have a website. It's called a public docket through
21 the federal register, which is just the way that people
22 in the real world can talk to people at FDA.

1 It's open until June 18. So you have two
2 months for you to comment on something if something
3 really was interesting, you got more to say, you can
4 send it in. Or if you have friends, loved ones, others
5 who you think have something to say, you can encourage
6 them. Anyone is welcome to comment, so you don't have
7 to be an individual or a family member.

8 But I'm going to -- you can submit as
9 anonymous. And I want you to keep in mind that if you
10 submit to the public docket -- that is -- the word
11 public is there for a reason -- this will go on the
12 website. So please think about how much personal
13 information you want to share. And we don't need your
14 personal information. Again, we don't care who -- what
15 your name is or where you live. We care about what
16 your experience is. So keep that in mind.

17 And so by -- you can just say anonymous,
18 anonymous, or just leave the blank parts for what --
19 when they ask what your name is.

20 Okay. So here's how you do it. You can go to
21 this website and click now. And if you go to our
22 webpage -- we hopefully have simplified things a bit as

1 much as we can.

2 Okay. There's a few rules that are very
3 important to go through, and I say this with all
4 seriousness about this meeting today. We want to hear
5 from individuals and family members and we really hope
6 that we have made this as welcoming as possible so you
7 feel comfortable lending your voices.

8 Advocates -- we have a lot of individuals in
9 the room and so advocates we're going to ask you to
10 play it by ear. If you're an advocate and you wear --
11 we all wear many hats -- if you also have personal
12 experiences, please put that hat on and speak from your
13 personal experiences living with OUD or having a family
14 member.

15 Everyone else is here to listen. That means
16 FDA and our colleagues from NIDA, they may have some
17 follow-up questions. You might have questions for us
18 and we may not be able to answer all of them, but we
19 are noting all of your questions. And if you come up
20 to us individually, we can take your information and
21 try to answer your question individually, even if we
22 can't answer them all today.

1 If you're here from a drug developer or a
2 healthcare provider or other interested person, we ask
3 you to just stay in listening mode. Remember that open
4 public comment at the end of the day is where you can
5 comment on other topics.

6 The views expressed today are personal
7 opinions -- they are not just opinions, they are
8 personal stories. And everyone has their own story and
9 their own perspectives and we respect that. Respect
10 for one another is paramount.

11 We will have differing views on things today
12 and differing experiences and we will listen to it
13 respectfully. We will not spend too much time on any
14 one given perspective, so we'll be moving along.

15 Our discussion is going to focus on health
16 effects and treatments. We know that this is a very
17 complicated issue and there are many concerns and many
18 things that -- questions you have and things you have
19 to think about living with OUD and getting the support
20 you need. Those are all important.

21 We will be focusing, though, on health effects
22 and impacts and treatments. Again, there's the docket

1 too. You know, you can send us comments through the
2 website for other things.

3 Okay. Again, for the respect of our
4 participants who are showing great courage in coming
5 here today, no audio recording, video recording or
6 photography.

7 And please complete evaluation form. We have
8 done 25 meetings that are sort of -- that are very
9 similar to this. We learned from every single one of
10 them, and so your feedback is important.

11 Okay. So with that said, I'm going to ask you
12 to get your clickers out. Advocates, you can answer
13 the first clicker questions, the first couple of
14 clicker questions too. And I'll then ask you to put
15 them down after a few minutes.

16 So here's how the -- I will read the questions
17 out, because it can sometimes be wordy. And as you
18 feel comfortable, you're going to click whatever letter
19 I say for that.

20 So where do you live? Do you live in the DC
21 area, the Metropolitan area, including Virginia and
22 Maryland suburbs? I'm going to guess, Baltimore, you

1 don't consider yourself a suburb of DC, so you don't
2 have to answer within Washington, DC. So if you live
3 within DC, A. And if you live outside of DC, B.

4 And I don't see any responses happening. Has
5 anyone -- someone has clicked, right? Okay, so let's
6 see. Okay. You know what? We will come back -- okay,
7 hold -- okay, so we're going to skip the first one.
8 That was -- okay, all we can do -- okay. Try again.
9 We learn from every meeting.

10 Where do you live, inside DC? Or outside of
11 DC, you will click B. Let me see if we're getting --
12 I'm not seeing any responses.

13 SPEAKER: I was thinking about it.

14 DR. EGGERS: Is it thinking? No. Okay, you
15 know what we're going to do? We're going to skip on
16 the polling questions. We have a lot of ground we want
17 to cover. We'll come back to those if we can them up.

18 And remember this is a federal government
19 agency, so sometimes our --

20 (Laughter)

21 DR. EGGERS: -- technology is -- so let's start
22 with our panel commenters. Just don't pay any

1 attention to the screens.

2 (Laughter)

3 DR. EGGERS: So we have two in person and two
4 over the phone. And I'm going to -- and again, they're
5 going to share their stories to kickoff our discussion.
6 So I'm going to ask Andrew to start. They've prepared
7 about three minutes of comments. And, Andrew, click
8 the red button, bring that microphone as close as you
9 can. You guys will let us know if you can't hear.
10 Okay. So thank you.

11 PANEL #1 DISCUSSION ON TOPIC 1: HEALTH EFFECTS AND
12 DAILY IMPACTS OF OUD

13 ANDREW: Thank you very much. So my name is
14 Andrew Kasoulis (phonetic) and I am a person who is
15 long-term recovering from OUD. That's mean, first and
16 foremost, as in "mom has her son back." And I
17 literally still can't even write that without almost
18 crying.

19 Our family continues to heal. And I've come
20 to understand that where you find recovering people,
21 you find recovering families, you find recovering
22 communities as well. Mom's not the only one that

1 benefits in the family.

2 I'm also a grad student at the University of
3 Southern Maine, where I'm pursuing a master's degree in
4 policy planning and management after achieving bachelor
5 of chemistry this past May.

6 While at USM, I helped co-found the Recovery
7 Oriented Campus Center, the ROCC -- at USM, we are rock
8 stars, rocking our way to college degrees -- and the
9 first of eight main chapters of Young People in
10 Recovery, YPR.

11 In 2007, however, I developed OUD under the
12 care of a healthcare provider following a work-related
13 back injury that would forever change my life. Nearly
14 four years were spent in and out of physical therapy,
15 undergoing two back surgeries that they don't even do
16 anymore because they have been so unsuccessful.

17 Often plagued with so much pain that I would
18 sometimes have to actually crawl to the bathroom just
19 to get there. I was quickly prescribed high doses of
20 opioids.

21 Once a high school lacrosse captain and three
22 times sports all-star and a collegiate football player,

1 I became restricted to the living room essentially and
2 became a slave to my OUD.

3 My physicians, like many other physicians,
4 were ill equipped to prevent, identify and/or address
5 OUD. There was no mention that the opioids also treat
6 the emotional and mental trauma that goes along with an
7 injury and I had no idea that there was a component of
8 that. A physical injury that changed my life, you
9 know, had an emotional shift and a mental shift, an
10 emotional trauma and mental trauma.

11 And then months into my OUD, I was abruptly
12 cut off by my prescriber. With no discharge plan and
13 no insight into other possible services, I experienced
14 intense physical withdrawals, some which were
15 mentioned, which of course included diarrhea and
16 vomiting.

17 What I was not expecting was the insomnia. I
18 was unable to sleep. And additionally, the feeling of
19 these bugs like crawling underneath my skin and chewing
20 their way through my body, that was something that even
21 if I was told about it, I don't think I could have been
22 prepared for. And far worse were the intense emotional

1 cravings.

2 Without opioids I was a failure, I was a loser
3 in my head and I was a roller coaster of rage and
4 depression in my heart. I seemed just completely
5 useless and worthless, weak and pathetic. And what a
6 waste of time and space I was. That was kind of my
7 internal monologue.

8 Again, I felt a prisoner in my own home and my
9 own mind and I was unable to leave either without the
10 assistance of opioids. And please understand what I
11 mean.

12 With opioids I was more physically able,
13 sometimes mentally unstoppable and always at a minimum
14 I was emotionally invincible. I was just unfazed by
15 things. My best days were spent laughing and engaging
16 and connecting with friends and people in my community.

17 I would temporarily feel free and desperately
18 sought that sense of security in any way possible. The
19 opioids indeed became my best friend and my partner.

20 And at that point, I'm not sure which, you
21 know, life someone would choose. You hear that term
22 choose a lot. And which life would you choose if you're

1 faced with those options?

2 Logically, I turned to illicit avenues of
3 satisfying and supporting my physical, mental and
4 emotional cravings. I purchased illicit opioids drugs
5 and developed a criminal lifestyle -- the only
6 community with which I actually felt welcomed,
7 curiously, and a part of, a real part of -- a sense of
8 community there.

9 I could not keep jobs or relationships. And I
10 became so desperate to find relief from all this pain
11 that I eventually turned to heroin. My worst days
12 included crimes that I'm reluctant to talk about here.
13 I would maybe say them and then say allegedly.

14 (Laughter)

15 ANDREW: In short, the use and the lifestyle
16 became incredibly traumatic in and of itself.
17 Emotionally bankrupt and mentally exhausted, I came to
18 a place where the only thing resembling relief came in
19 not living.

20 Unaware that I had developed a very, very
21 severe depression along with OUD, I attempted suicide
22 through intentional overdose.

1 What still certainly holds me in terror is the
2 idea of needing further back surgeries, which is almost
3 guaranteed with my condition. Chronic pain is a huge
4 part of my story. I do a lot of yoga and meditation
5 and stretching to manage that.

6 I certainly hope I can stay on the path of
7 recovery and find effective non-opioid based pain
8 medications, but what most concerns me is the
9 discrimination and stigma that people with OUD face on
10 a daily basis.

11 And I can tell you about, you know, how I was
12 chained to my past and told, you know, that my present
13 defiance is defined by my past, i.e., the tail wags the
14 dog. If there's not a dog with a tail -- the tail wags
15 the dog; the wake steers the ship.

16 I think this is best summed up with an
17 experience of a friend of mine and a colleague who
18 landed a fellowship at the White House Office of
19 National Drug Control Policy. He literally went
20 through an NSA clearance, a full NSA clearance, had a
21 badge that said executive office of the president and
22 he could not rent an apartment right here in DC because

1 he's a person with a felony drug conviction due to his
2 OUD.

3 He actually had to pay someone -- transfer
4 money to a friend of a friend of a friend in California
5 to sublet a room. And I think that kind of really sums
6 up in a very tangible way what -- you know, some of the
7 things we're dealing with.

8 Lack of prescriber and public education around
9 OUD continues to prove very negatively, impactful on
10 the lives of millions of Americans.

11 Fortunately, I am just one of millions of
12 pretty awesome and incredible and aspiring recovery
13 stories, which I really hope that we can elevate and
14 celebrate. And I beg of you in this room to identify
15 as recovery allies. If you're not personally in
16 recovery, to your family, to your friends and in your
17 communities to help raise those stories and elevated
18 those -- that inspiration and that hope because it's
19 happening all over the place.

20 Again, I'd like to strongly support the FDA's
21 recent initiatives related to OUD and hope that the
22 patient perspective continues to be well represented.

1 And I appreciate your consideration of my experience
2 and offer myself for any questions that anyone might
3 have here or later. And thank you very, very much.

4 DR. EGGERS: Thank you, Andrew. Thank you.

5 (Applause)

6 DR. EGGERS: We'll save questions for now, but
7 then we'll have the -- facilitate a discussion. I'm
8 going to see if we could have Pamela on the phone.

9 PAMELA: Hi. I'm here. Can you hear me?

10 DR. EGGERS: Hi, Pamela. Thank you so much.
11 Yes.

12 PAMELA: Thank you for the opportunity. Hi,
13 everyone. I am a person also in long-term recovery
14 from opioid dependency. When opioid dependent, opioid
15 used to -- sort of drove my daily activities as I would
16 be drug sick if I didn't first attend to my opioid
17 dependency.

18 Opioids do not cause confusion if you're
19 taking in appropriate amounts. Most opioids addicts
20 don't use excessively because they know they have to
21 have a continual supply of opioids or they're going to
22 be sick. So you don't ever have extra. Extra is a

1 foreign concept in terms of opioid use disorder.

2 The effects of opioid withdrawal were
3 insurmountable. I could not function in my home life
4 or work life if I was in withdrawal. I threw up a lot
5 and then got very dehydrated and was usually requiring
6 a hospital stay to withdraw toward the end.

7 I remember once trying to stop using opioids
8 while living and working in Paris. I presented at an
9 ER and they quickly whisked me off to a cardiac unit
10 reminding me that I had heart valve problems from
11 having been an injector for so long.

12 I craved opioids and tried to use before work
13 and after work only, but sometimes would use at lunch
14 or would sneak around to different floors' bathrooms to
15 inject within my workplace.

16 When someone has an opioid dependency such
17 that they are going to be drug-sick when they don't
18 use, nothing will take precedence over finding some
19 opiates to get unsick. Once unsick, I could perform my
20 job responsibilities and my daily living activities. I
21 had minimal relationships with my family members when I
22 was opiate dependent because they did not approve of my

1 heroin use. They were not mean, but I was ashamed and
2 could not stop although I wanted to. I decided I would
3 rather die than continue to live a slave to addiction.
4 So I attempted suicide, obviously unsuccessfully.

5 I had a lot of medical problems from my
6 injecting heroin and cocaine. I was diagnosed with a
7 level IV staph infection and could not walk from sepsis
8 in my knees and back. I had an abscess that had
9 floated to my spine which was also very painful.
10 Because doctors were fearful I would use a PICC line
11 for drugs, they would not put one in to administer the
12 IV antibiotics that I needed. I also had no insurance
13 at the time, so that may have been why they wouldn't
14 put in a PICC line.

15 They kept having to redo peripheral sites to
16 administer the IV antibiotics which was difficult
17 because of how heavily vena compromised I am. It took
18 me a long time to get rid of the MRSA completely. I
19 had stopped using and got a mosquito bite which turned
20 into a MRSA abscess. I had an ingrown hair which also
21 turned into a MRSA abscess.

22 I am a reasonably intelligent human being. I

1 graduated University of Michigan-Ann Arbor, speak 4
2 languages and hold a master's degree. However, nursing
3 and medical staff often treated me as stupid because of
4 ignorance about the emotional roots of this disease.
5 Establishment needs to stop tying addiction to the
6 intellectual realm. Addiction has nothing to do with
7 intellect.

8 If anything, strong intellect is a risk factor
9 for the disease of addiction because people who are
10 strong intellectually believe that they can outthink
11 the disease of addiction, which you cannot.

12 Last week I went to the doctor for an annual
13 physical. I was so excited and proud of the fact that
14 she had no idea that I had been cocaine and opiate
15 dependent for nearly 30 years of my adult life.
16 However, I have advocated doing the lab draws -- I'm
17 sorry, however I have avoided doing the lab draws that
18 they required because I know that once I go to the lab
19 and they can't draw blood out of my arms, 15 years into
20 recovery, I will then be treated completely differently
21 as an addict.

22 I now am a person in long-term recovery and it

1 took me really 30 years to get 15 consistent years away
2 from cocaine and opiate use. I am one of the most
3 fortunate. I have a loving family and a mother that
4 never gave up. I come from privilege, education and
5 resources and I was therefore empowered enough to find
6 harm reduction early on, 1994, and believe that the
7 changes in thinking that harm reduction programming
8 provided me were essential to my long-term success and
9 overcoming a traumatic and chaotic addiction to opiates
10 and cocaine.

11 I have broken the generational cycle of
12 chemical dependency in my family. Both my father and
13 grandfather used alcohol. What worries me most about
14 my condition now is the fact that my children are
15 living with the effects of heavily altered genes. I
16 didn't realize that by waiting to have children when I
17 was fairly confident that I was finished using I was
18 then giving my children genes that had been heavily
19 impacted by my very heavy drug use. The cocaine did
20 the most damage, I believe.

21 I also worry about how much stress I put on my
22 heart with the years of heavy cocaine injection. I

1 worry most about my children being discriminated
2 against if people where we live were to know my true
3 addiction history. Thank you again for your time today
4 and for the opportunity to speak.

5 (Applause)

6 DR. EGGERS: Thank you, Pamela. You can't see
7 us, but there have been -- you've got a lot of head
8 noddings and just reactions that mean that people know
9 what you're talking about and the story you're sharing,
10 so thank you.

11 Before we let Pamela off the phone I just want
12 to see if there is any clarifying questions from our
13 FDA experts. Okay, all right, then Pamela, thank you
14 so much. Again, you can participate through the
15 webcast and we hope that you keep commenting. That was
16 a very powerful story.

17 PAMELA: Thank you.

18 DR. EGGERS: Thank you. Okay, now we're going
19 to go back into the room and we will have Amanda to
20 bring that mike as close as you -- there you go.

21 AMANDA: I think I'm good, I'm pretty loud.
22 Hi, my name is Amanda. I am a peer recovery outreach

1 worker for Baltimore County Department of Health,
2 Bureau of Behavioral Health. I am also a person in
3 long-term recovery from opioid use disorder and I am
4 living with and the caretaker of a person with chronic
5 pain that has now begun to acknowledge that they have
6 an opioid use disorder as well.

7 I started using opioids when I was about 16
8 years old. I was prescribed them for a wisdom tooth
9 removal and there were a lot of medications in my house
10 and used, started off purely recreationally. By the
11 time I went to college I was a weekend partier, I would
12 say first year of college it became a daily thing.

13 After a bad relationship I moved from simply
14 using prescription opioids to being an active IV drug
15 user. I had convinced myself that I was the safest IV
16 drug user you have ever seen in your life. I had been
17 able to swindle Sam's Club into giving me those giant
18 boxes of needles. I never used the same needle twice.
19 I had a pill filter. I understood the uses of Narcan
20 and naloxone and I kept them and I always used with a
21 buddy.

22 And that made me feel like I had it completely

1 under control. I did have gate (phonetic) shots, so I
2 knew exactly how much I needed in order to function. I
3 was using pharmaceutical pain medication as well as
4 heroin at the same time. I also was using benzos on
5 muscle relaxants. Most of those medications were used
6 when I wasn't able to get a hold of an opioid and I
7 wanted to be able to manage my withdrawal and continue
8 going to school and work, which I was doing full time.

9 My bad decisions buddy decided to go pick up
10 with me and the person that she used heroin with first
11 had just come back from rehab. The person did not have
12 any money and was willing to do things in order to get
13 heroin that I was not comfortable with and I was
14 watching the car of that transaction happen. I
15 realized that I didn't know how long it was going to be
16 until I decided that that was something I was willing
17 to do.

18 I went home, I used, I called my parents and
19 that was it. My parents knew that something was going
20 on. I don't think that they thought it was opioid
21 dependency. I believe they thought it was probably
22 alcohol and marijuana and I feel that they had gotten a

1 hint within the past 6 months that a good quantity
2 prescription medication was coming from my parent's
3 house. I went into treatment, I detoxed and I decided
4 that the only way that I was going to survive was if I
5 was extremely open and public about my substance use
6 and my recovery from the very beginning. I was open
7 and public about the fact that I had gone into
8 treatment. I was open and public about the fact that I
9 was in IOP. I was open with my employer as to why I
10 needed to change my work schedule. So I've never lived
11 anonymously.

12 It took a very long time for the person that I
13 care for to recognize the similarities between my story
14 and their story. It was -- I would say it was within
15 the past 6 months and it was through the conversation
16 of preparing to come here that they were actually able
17 to sit down and look at what was being on these opioids
18 costing.

19 They are on an intrathecal spinal morphine
20 pump in addition to oral medication. The pump has been
21 wonderful and when there is no crisis, very little oral
22 medication is taken. The oral medication that they

1 take is contraindicated to the opioids though. It's a
2 lot of muscle relaxers and benzos.

3 When it's bad, it's very bad. When the pump
4 isn't enough, when the medication needs to be
5 increased, when we're in the emergency room and they
6 are in full crisis they experience full body muscle
7 spasms. For all of you out there if you've had a
8 Charley horse now imagine your whole body is Charley
9 horsing simultaneously at the same time and it does not
10 stop. We've let them go for 4-1/2 hours. Then you're
11 watching someone scream for 4-1/2 hours.

12 The new thing that's happened over the past
13 couple of years is that they will actually pass out and
14 stop breathing which is great because we can straighten
15 them out, it's bad because they're not breathing. They
16 will come back around, take that deep breath like
17 they're coming out of water and then seize up again.
18 Large amounts of medication is now needed in order to
19 get those spasms under control because of the tolerance
20 that has built up from years of opioid use. The fear
21 that I have is what happens when I'm not strong enough
22 to not go to the lockbox that I know I'm smart enough

1 to crack and decide to use again and what do I do if
2 the reason why I'm using is because I'm experiencing
3 the trauma of that person in the emergency room in
4 crisis again. And what do I do when a hospital doesn't
5 do what I know is needed to keep that person out of
6 crisis because they have decided that that pump just
7 magically makes pain disappear, that when they see the
8 amount of medication that this person is on that they
9 don't need anymore.

10 And now I'm in the hospital for 3 weeks and
11 now I'm watching them scream. It's a vicious cycle.
12 And hearing that person finally admit that being stuck
13 in that vicious cycle of pain has a lot to do with why
14 so much medication is needed. Hearing them say that
15 what happens when the body's tolerance level finally
16 breaks and they just OD. What do we do when that
17 happens and that pump is running and we have no ability
18 to turn it off? What do we do when the pump does stop
19 working because we've watched that happen too and the
20 withdrawal is almost instant because you have a stream,
21 a steady drip of morphine going into someone's spine.
22 I have seen this person try to find the balance between

1 managing pain, embracing a child with substance use
2 disorder and being strong enough to do what's needed,
3 to do the bio feedback treatment, to do the counseling
4 that's necessary, to constantly be talking to doctors
5 about their condition and find a way to be the best
6 patient advocate they can and sometimes that means
7 sitting in an ER and saying yes, you can try that 1 mg
8 of Dilaudid and know it will do nothing. Thank you.

9 DR. EGGERS: Thank you, Amanda.

10 (Applause.)

11 DR. EGGERS: And now we're going to go back to
12 the phone and have Jody.

13 JODY: Hi, can you hear me?

14 DR. EGGERS: Yes, we can. Thank you, Jody.

15 JODY: Okay, am I loud enough for--?

16 DR. EGGERS: You are, and you've got a lot of
17 people here welcoming your comments.

18 JODY: Great, okay, good morning. My interest
19 in the comments today in this topic might be a little
20 bit unique in that it stems from three different view
21 points. One is as an opioid user myself, sometimes
22 scared, angry, confused, about the treatment I receive

1 as a patient in today's climate being told I need to
2 get off the opioids that I've taken for years as a way
3 to treat my pain and other symptoms, but not given an
4 alternative and left to deal with not only the pain,
5 but now also the withdrawal.

6 Added to this is suddenly trying to come to
7 terms with hearing things like I'm an addict and an
8 abuser and the disrespect that goes with it when I have
9 been more familiar with people describing me instead as
10 a go-getter and a professorial and other terms. Second
11 is also as an opioid user, but this point of view is
12 one is someone who is often worried that I might be the
13 next one to unwittingly take a lethal combination of
14 prescribed medications or prescribed meds with
15 something like, you know, for a cold and not wake up
16 the next morning and becoming the next statistic.

17 The third point of view is as the mother of a
18 child who became an addict after being treated with
19 opioids following an automobile accident. She hid her
20 addiction from everyone except a couple of her co-
21 addicted friends and went on to get married, to have
22 two children, get her master's degree and in fact was

1 working on her Ph.D. when she died of an accidental
2 overdose at the age of 37 after taking methadone and an
3 opioid.

4 She never asked those who loved her for help,
5 but she was finally looking for it. So I'm tired of
6 the drugs taking away my stamina, making my speech
7 slow, making everything foggy. I could sleep all day,
8 I've gained weight. I've got a constant headache and I
9 never really want to do anything.

10 I've got scabs from itching and scratching all
11 the time. But without the drugs I can't treat the
12 effects of my medical conditions. I can't perform the
13 functions of my job because I am unable to get to a
14 lengthy meeting or make presentations. I can't go to
15 the dentist, the eye surgeon, which I need to do on a
16 monthly basis for a condition. I can't go to a movie
17 or a concert, take my grandchildren to the zoo or take
18 a long flight to see the ones that aren't local.

19 My husband has to sleep in another room so at
20 least one of us can get some rest. I've begun tapering
21 off my opioids on my own at the urging of my primary
22 care physician, my pharmacist, my health insurance

1 company because everyone is making it more difficult to
2 get the prescription, even though the prescribing
3 specialist don't feel that they have a good pain
4 management plan or any other drugs to replace it.

5 I've had some success doing this on my own.
6 For instance, one dosage was 75 mg daily that I was
7 taking and now I'm down to 30 mg of that drug a week,
8 but sometimes I don't know if the unsettled feeling,
9 the anxiety, the craving, the crawlings and other such
10 things that I often have is from the opioid withdrawal
11 or just from trying to deal with pain. The feelings
12 are there, I just don't know what's causing them more.
13 So now I as a self-proclaimed control freak am not only
14 unable to control my pain, which drives me nuts, but I
15 also can't control my pain control medication either.
16 It's controlling me.

17 The government regulations are controlling me.
18 The pharmacies are controlling me. Some providers,
19 everybody else is trying to drive my bus and that
20 something that I have always, you know, really held
21 close to my vest as being a control freak trying to do
22 it myself.

1 So I'm hoping there is a way to work through
2 this crisis providing respect to everybody who has so
3 far been shown so much disrespect in all of this, but
4 only helped to return to a stable, meaningful life and
5 I'm fearful that otherwise too many of us will choose
6 no life instead of a life where we're left trying to
7 navigate without adequate support and assistance where
8 needed because it really does feel that helpless and
9 that hopeless.

10 DR. EGGERS: Thank you very much, Jody.

11 (Applause)

12 DR. EGGERS: Can we -- had you finished your
13 comments, Jody? You were -- okay. Jody, you couldn't
14 see us in here, but again you had a lot of head nods,
15 there are a lot of people who share similar experiences
16 or perspectives as you do and I think we'll -- were
17 there any clarifying questions for Jody. Okay. So can
18 we give another round of applause for our panel
19 members?

20 (Applause)

21 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 1

22 DR. EGGERS: Thanks. You can sit up here or

1 you can go back to the table if you like. Okay.
2 Hopefully you heard some of your own experiences and
3 perspectives shared in that. Can I have a -- if you
4 feel comfortable I'm going to ask for show of hands, so
5 however you feel comfortable, whether you're a family
6 member or an individual or even an advocate, speaking
7 on behalf of others, did you hear yourselves, okay I'm
8 getting head nods, so we will take that as yes.

9 We started a little bit late so we're little
10 bit short on time. I'm going to do a time check at
11 12:00 o'clock. We might go a little bit over 12:00
12 because I think we can have lunch in 45. But again, if
13 you need to go use the restroom or any time get up,
14 please do.

15 We had some polling questions that we tried
16 earlier and so we're going to try them again. I think
17 it should be working. So if you can get those clickers
18 out. These are important to us. Please, if you're
19 looking at the results of these polling questions, they
20 are not a scientific survey in any way, we do not treat
21 them as such. They are just a chance for us to get a
22 sense of who is in the room and who is on the web.

1 And so it's a -- and so this helps us
2 understand where you're coming from literally and what
3 your experiences are. So where do you live, if you can
4 get to clickers, and we'll try it again. If you live
5 inside D.C. area A and outside the D.C. area B. I'm
6 seeing the numbers go up. That's great.

7 And if you're on the web, if you haven't taken
8 the polling, then you should be able to do so too.
9 Okay, all right. So I don't see the numbers go up
10 anymore. So we can take this answer. That's a tricky
11 button. I think I saw the majority of people were not
12 from the D.C. area, so, okay, all right. Okay.

13 So before I -- before you click your buzzers
14 on here I'm going to -- let me read through this, okay,
15 so let's go back to the -- okay. So we thank you for
16 traversing the beltway. And for those of you who had
17 taken the Red Line this morning, a special thank you.
18 I heard there was a fire on the Red Line.

19 Okay, so next question. Okay. Which
20 statement best describes you? An individual who
21 currently struggles or struggled in the past with
22 opioid use disorder or opioid addiction or abuse, a

1 family member or caregiver of such an individual or an
2 advocate for individuals who struggle with opioid
3 addiction or abuse.

4 If you wear two hats, I hope you feel
5 comfortable that you can share that you are that
6 individual or family member. So you can only choose
7 one, so if you wear two, think about choosing A or B.

8 SPEAKER: Sara, we're going to have to
9 continue this question. This is not going to be as
10 accurate. This only captured some of the responses --

11 DR. EGGERS: Okay, all right, well let me just
12 make a point here. There are a lot of individuals
13 struggling with opioid abuse and addiction in person
14 and on the phone and we thank you from the bottom of
15 our hearts. We also have family members and people who
16 are advocates. So let's move on, okay.

17 Now -- from now on I want you to think about
18 yourself or that loved one who has opioid use disorder,
19 one person, so advocates if you only wear that hat then
20 please don't answer these questions. I want you to
21 think of one person, yourself or someone else and how
22 old, what is your age? A younger than 18, B if you're

1 in the 18 to 29, C if you are in 30 to 39, D if you're
2 in your '40s, E if you're in your 50s, and C if you're
3 60s or better -- F, yeah, sorry, sorry.

4 Okay, let's go on to see what we get.

5 SPEAKER: Okay, okay, okay, okay. We don't
6 have kids represented in the room. Hopefully if there
7 are parents or adolescents on the webcast and you can
8 write in, but otherwise it shows that opioid use
9 disorder doesn't care how old or young you are and so
10 we have a spectrum here. Okay, let's move on. We'll
11 get all the web in a second. Okay. So that's fine.
12 Okay.

13 So do you or your loved one identify as male -
14 - female -- sorry, female A, B male or C other? Okay.
15 Again it doesn't -- and we have a mix here, let's move
16 on. Okay, how long has it been since you or your loved
17 one first started using opioids of any kind or okay,
18 now start clicking, A less than 5 years ago, B 5 to 10
19 years ago, C 11 to 20 years ago, D 20 to 30 years ago,
20 E more than 30 years ago, or F you're not sure. And
21 exact numbers don't matter. Just trying to get a
22 sense. Okay. Okay, we have a range of experiences

1 here and years living with this condition. Okay, I
2 think is that the last polling question? One more,
3 okay.

4 Have you or your loved one ever been diagnosed
5 by a healthcare professional as having an opioid use
6 disorder or addiction? Okay. What this shows, we have
7 75% of you in the room have been diagnosed, there is
8 25% who have not been part of the healthcare system for
9 opioid use disorder, have not been diagnosed for
10 addiction in the room. Can we have a summary of what's
11 on -- okay, we have one more polling question.

12 Sorry, there is supposed to be a break in
13 between some of these, so. Okay, have you or your
14 loved one ever had the following conditions, acute pain
15 for which a medical treatment was sought. This would
16 be something, broken bones, dental work post surgery.
17 I think Amanda that's -- chronic pain, neuropathic
18 pain, cancer posttraumatic. C, other substance use
19 disorder, alcohol, amphetamines, cocaine,
20 hallucinogens. D, psychiatric or mental health
21 conditions, depression, anxiety, mood disorders or
22 others or E, other health conditions that you think are

1 relevant to what we're talking about today. You can do
2 more than one, all that apply. While we're doing --
3 while we're waiting for that, can we have a summary of
4 what's on the web?

5 GRAHAM: Yeah, we have about 65% saying acute
6 pain for medical treatment, 37% chronic pain, 45% other
7 substance use disorder, 51% psychiatric or other mental
8 health conditions and then 21% other health conditions.

9 DR. EGGERS: And generally for the other
10 demographic questions were they similar?

11 GRAHAM: It's very similar, yes.

12 DR. EGGERS: Were there any pediatric, any
13 kids?

14 GRAHAM: There were no pediatrics, but there
15 was 37% between 18 and 29.

16 DR. EGGERS: Okay, all right, okay, thank you.
17 So what this does -- so again it's across the board of
18 the other conditions that you are having to manage and
19 live with at the same time. Okay. What this has done,
20 it's been very helpful for us, even though it's been
21 probably a bit tedious for you to do the polling. It
22 gives us a sense of again who you are without saying

1 your names and what your experiences are.

2 Now, let's talk about our -- what we're here
3 to talk about which is what it's like to live with
4 opioid use disorder. We're going to -- I'm going to
5 have to have you do one more polling question for --
6 but then we'll get into raising your hands and
7 speaking. And the first polling question asks you, I
8 think, about making tradeoffs about the big -- the
9 general bothersome health effects that you are facing
10 and then we're going to get into more specifics.

11 So if I ask you in general what are the most
12 bothersome health effects related to your or your loved
13 one's opioid use disorder, you can choose up to two
14 things. So it can be the health effects associated
15 with the use of opioids, like we heard Jody talk about
16 some of those. It could be symptoms associated with
17 opioid withdrawal or drug sick as we heard. Symptoms
18 associated with the cravings -- however you think of
19 the word cravings, symptoms associated with that or
20 health effects. Symptoms related to your underlying
21 health condition that we just asked you about or some
22 other big bucket of health effects that we haven't

1 mentioned.

2 Okay. Okay. Let's see. And on the web get a
3 summary.

4 GRAHAM: On the web we have about 70% for
5 health effect associated with use of opioids, about 38%
6 for symptoms associated with withdrawal and cravings
7 and about 27% on symptoms because of an underlying
8 condition.

9 DR. EGGERS: Okay. All right. So you're
10 dealing with everything and you're having to balance
11 these effects. We heard that nicely from our
12 panelists.

13 Would anyone like to start with -- anyone like
14 to share more stories about health effects with the use
15 of opioids like we heard Jody talk about one the phone?
16 Anyone like to share some experience about the effects
17 of using opioids that are the most bothersome to you.
18 And we'll go right back with --

19 ANONYMOUS: Okay. My name is --

20 DR. EGGERS: And you can state your name if
21 you want.

22 SHARON: Okay. My name is Sharon and as far

1 as health effects of using heroin for myself, I used
2 heroin for 40-plus years. I'm now on methadone
3 maintenance program. Thank God. And I still have
4 scars from my injecting heroin, you know, and people
5 notice it. And there was one time I wouldn't leave the
6 house without long sleeves on, 102 degrees I had on
7 long sleeves but I've gotten a lot better about it now,
8 you know. I mean I did it to myself. It is what it
9 is, it's not going to change. So I'm dealing with it
10 and people who don't care to look don't look, you know,
11 so -- you know --

12 DR. EGGERS: Thank you so much.

13 ANONYMOUS: You know.

14 DR. EGGERS: Thanks. One other -- so, right
15 here.

16 MONICA: Thank you. My name is Monica. I'm a
17 person in long-term recovery. What that means is that
18 I haven't had a mind or mood altering substance since
19 over 12 years. The effects that I still have from the
20 effects of the use of opioids, I have chronic
21 constipation even after being in recovery for 12 years.
22 I still have to take something to assist me in being

1 able to go bathroom normally. On average I sleep about
2 4 to 5 hours a night. When I first became a person in
3 recovery I didn't sleep for 62 days even with the help
4 of mental health medications like Trazodone and
5 Seroquel to help me sleep. I may have slept maybe 2
6 hours per night. So now on average I may sleep about 5
7 hours. So these are some of the long-term effects of
8 me using heroin. I did use heroin for over 24 years
9 and even being in recovery for 12 years these are some
10 of the long-lasting effects that I still deal with on
11 daily basis after using -- after not using heroin for
12 that amount of time.

13 DR. EGGERS: So great comments about the --
14 that the effects can last -- the effects of the opioid
15 use can last well beyond the use of the opioids.

16 Let's move on and talk about cravings. And
17 first I want to ask, you know, we struggled with this
18 term and so we would like to know how -- what does this
19 term mean to you, this idea, and what words do you use
20 to describe whatever feelings you might consider to be
21 cravings?

22 AMANDA: Do you want to know in the beginning

1 like right when you -- like while you were in active
2 use? Or do you want to know what it's like now? Or
3 you want to know both?

4 DR. EGGERS: Both is good.

5 MS. AMANDA: It is feeling uncomfortable in
6 your own skin and in the pit of your chest. And in
7 your mind it is the occupying force that is driving
8 you. It is everything hurts and you know that once you
9 get that first bit in it's going to make everything
10 released. It's you're going to not be locked up,
11 you're going to be able to finally relax. That feeling
12 of fight or flight is going to subside, that's in
13 active use.

14 Today, you know, I'm 7 years in and it's -- a
15 lot of it has to do with when I am put into a fight or
16 flight feeling when I have that feeling of being on
17 edge and I am getting tied again and feeling that push
18 in my chest my brain goes, you need drugs, that's what
19 you need, that's going to solve this problem, and
20 that's the first response. And that's the first
21 response that's going to be in my head probably for the
22 rest of my life. It's quiet but it's there and I have

1 to use other tools to help deal with that. And the
2 more stressful a situation is, the more physically
3 painful a situation is, the worst that craving feeling
4 has.

5 When I was getting ready to have my first
6 child, you know, you've got moms that are concerned
7 about everything under the sun when they're about to
8 have a baby. My concern was how am I going to handle
9 being in pain because it's going to cause craving and I
10 know that, and can I do this without an epidural and
11 without pain medication afterwards because I am
12 petrified of putting that in my body. Not because of
13 the baby but because is that going to be the thing that
14 sets me off.

15 DR. EGGERS: Thank you, Amanda. A lot of head
16 nods, agree with that distinction. But anyone else
17 like to follow-up on that?

18 ANONYMOUS: I have a question.

19 DR. EGGERS: Yeah.

20 ANONYMOUS: I want to know why -- how do I put
21 this -- I feel as though if we have something -- if we
22 have something as beneficial to the cocaine as we do to

1 the heroin, I don't think we will have as many users on
2 cocaine. You know what I mean? To buying 1 cap of
3 heroin you would buy 10 things of cocaine, you
4 understand what I'm saying? I'm saying is that if you
5 use both heroin and cocaine, right, I think if we have
6 something just as equal to the heroin as we did to the
7 cocaine, I don't think it could be justified. You know
8 what I mean?

9 DR. EGGERS: That's a very important point. I
10 think it's a bit beyond what we'll be able to talk
11 about in-depth today but we've noted that you've raised
12 the point about the challenges of having them both
13 together and the challenges of fixing either one of
14 them. So thank you for the comment.

15 DR. HERTZ: Sara?

16 DR. EGGERS: Yes.

17 DR. HERTZ: Hi. This is Sharon Hertz. I can
18 say that, well, today we're focused on opioid use
19 disorder. We are concerned about the fact that we
20 don't have treatments for other types of substances
21 with similar problems. And it is something that we're
22 working on with a number of other groups as well to try

1 and see what we can do to help facilitate management of
2 those disorders as well.

3 DR. EGGERS: Thank you. Okay. One other
4 person about cravings, we have right up here.

5 DENISE: Hi. I am Denise REDACTED, a parent,
6 caregiver. So I just thought I'd get a little insight
7 as to what that looks like for us to see our child with
8 cravings. In the beginning we can't wrap our minds
9 around it, but as we travel that journey it was the
10 first time that I looked at that desperation and really
11 understood what my son was going through. So those
12 behaviors instead of me saying how could he do this to
13 me, I realized that it was a symptom of their illness
14 and it allowed me to really put myself in their shoes
15 and allowed me to be part of that solution. So instead
16 of judging him and shaming him I did a better job of
17 understanding what he was going through in trying to
18 lift him up, and that was really important for us. So
19 I hope that makes sense from a caregiver perspective.

20 DR. EGGERS: Thank you. Very important
21 perspective. Okay. Yes, go ahead, Andrew.

22 ANDREW: I just want to share a story, kind of

1 experience I had a few years ago that smashed me in the
2 face one day. So I appreciate fitness, I try to stay,
3 you know, physically in shape. When I don't take care
4 of my body it degrades very, very, very quickly and I
5 end up in a lot of pain and bad things happen.

6 So I was meal-prepping, trying to eat healthy
7 as well and one day, you know, life happened and I
8 couldn't bring my lunch to school and so I was walking
9 down to the local pizza joint thinking I'm going to get
10 grilled chicken Caesar salad, you know, because it's,
11 you know, because fitness and I want to stay in the
12 track of health and wellness and I didn't even get to
13 the door and I started like sniffing in the air and I
14 was just like, oh, gees. You have a grilled chicken
15 Caesar salad because fitness and then as I opened the
16 door it like really hit me square in the face, this
17 intoxicating scent of pizza, right?

18 And then I looked over and I saw glistening in
19 a case under this warm heat lamp, and it was summer
20 time but I still wanted to just kind of like curl up
21 underneath that heat lamp with a pepperoni pizza and
22 just kind of like snuggle with it and all of a sudden I

1 was like off to the races in my head battling just
2 like, no, I'll be -- you know, fitness and you're doing
3 so good and you know what happens, Andrew, you know,
4 you eat one slice of pepperoni pizza and then you're
5 like getting buff chick wraps and, you know, you're
6 into the cookies and --

7 DR. EGGERS: I think it's a parallel story.

8 ANDREW: Yeah. And as I'm sitting there, and
9 by the way I got up to the line and I was like I'll
10 have a grilled chicken Caesar salad, while I wait I'm
11 going to have a slice of pepperoni pizza because I'm
12 not as strong as I'd like to think I am. But as I am
13 standing in the line waiting for my food it hit me that
14 is lunch, one afternoon. You want to talk about
15 cravings. That was just one afternoon lunch.

16 DR. EGGERS: Yeah, that resonate, that
17 resonate, yeah.

18 ANDREW: And I was like, whoa, this might
19 apply a little bit and I shared that story with law
20 enforcement, doing trainings with law enforcement
21 because they seem to be able to relate to that story
22 quite a bit.

1 DR. EGGERS: Thank you, Andrew.

2 ANDREW: Thank you.

3 DR. EGGERS: I'd like to see if there's any
4 webcast comments on craving?

5 GRAHAM: We don't have webcast comments on
6 cravings. We see people who are just echoing what
7 we're hearing in the room.

8 DR. EGGERS: Okay. Great.

9 GRAHAM: We have a couple on some of the other
10 health effects like social and emotional effects that
11 they're feeling and experiencing.

12 MS. EGGER: Okay. Great. We will be talking
13 about the social and emotional effects in a little bit.
14 Right now I'd like to go on to -- yes, Elektra. I'll
15 turn you, right.

16 DR. PAPADOPOLOUS: So I was wondering if maybe
17 we could see a show of hands of, you know, how many
18 think that cravings is the sort of most accurate term
19 and the one that you use the most and -- or how many
20 would use a different term to describe that sensation.

21 DR. EGGERS: So if you know -- you or your
22 family member or your -- in your support group use the

1 term cravings, can you raise your hand? Okay. Do you
2 use a different term, raise your hand? Okay. Let's
3 just go quick round. Yell out what you --

4 SPEAKER: Obsession.

5 DR. EGGERS: Obsessions, okay. Here, what do
6 you -- triggers. Okay. Other words?

7 SPEAKER: Urges.

8 DR. EGGERS: Urges. Okay. Great. Thanks.

9 ANONYMOUS: Feening is one that comes to mind.

10 DR. EGGERS: Oh, someone --

11 SPEAKER: Oh, okay.

12 DR. EGGERS: Okay, which, what word?

13 ANONYMOUS: Feening, as in feen, yeah.

14 DR. EGGERS: Feen, okay, okay. Great. Yell
15 out another one? Okay. Go with the microphone.

16 ANONYMOUS: (Inaudible)

17 DR. EGGERS: Yes, go ahead.

18 ANONYMOUS: It's more the process, it's not
19 just the substance craving itself. It's the act of
20 doing it, preparing it, consuming it, the immediate
21 relief afterward. You know what I mean? Like it's
22 this huge build-up and then, you know, volcanic

1 eruption type of thing. It's like -- that all alludes
2 to the craving, I guess, that goes with it.

3 DR. EGGERS: Great. Thank you so much. Okay.
4 One more, one more here.

5 ANONYMOUS: Got to have it mean you got to
6 have money and you got to scrub. Suppose you don't
7 have money to get it, you're going to go get sick.

8 DR. EGGERS: Okay. Yes.

9 ANONYMOUS: As simple as that.

10 DR. EGGERS: Thank you. That's an important
11 point. One more here.

12 ANONYMOUS: Anticipation.

13 DR. EGGERS: Anticipation. Okay. Okay. All
14 right. One more. One more and then we're going to go
15 onto withdrawal or drug sick.

16 ANONYMOUS: I just want to point out the
17 craving thing when it comes to methadone is similar to
18 opioid cravings with methadone and it can be described
19 in a different manner.

20 DR. EGGERS: Okay. All right. We're going to
21 talk about methadone in the afternoon, and please raise
22 your hand again. There's two same hats so I am going

1 to -- you should have worn different hats. Okay.
2 Let's move on to thinking specifically about reducing
3 use or abstaining from opioids. Whatever terms, we've
4 heard terms withdrawal, we've heard term drug sick, it
5 could be things in here that look like cravings to you.
6 But of these effects here we'd like to know what are
7 the most bothersome symptoms for you -- effects for
8 you. So if it's fatigue or lack of energy. Oh, you
9 could choose up to three things. Okay.

10 Fatigue or lack of energy, A. If it's
11 cognitive effects, so things that happen -- your
12 brain's not working the way you want it to be, you
13 know, you can't concentrate or we call brain fog. Is
14 that working? Okay. That's B. Anxiety, irritability
15 or jitteriness, and I think this might be the first
16 time we've used jitteriness as an FDA term but I think
17 you get the point, that's C.

18 Depression, apathy, boredom, D. E would be
19 insomnia or sleep issues like we heard about. F is
20 nausea, vomiting, or diarrhea. G is flu-like symptoms
21 such as fever or body aches. H is pain of any kind.
22 And I would be something else. So again what bothers

1 you the most? This is what we want to know. All of
2 them. Okay. We'll take that point that if you could
3 choose all of them you would. What are we seeing on
4 the web for this? Just generally, what's the most?

5 GRAHAM: Sorry. It looks like it's -- come
6 back in a second.

7 DR. EGGERS: Okay. I'll come back. Okay. I
8 think we can close out the polling here. Okay. Okay.
9 It's all of them, right. Okay. It's all of them, F.
10 Interestingly nausea, vomiting, and diarrhea has the --
11 is amongst the lesser things that you're experiencing.
12 It's outweighed by -- here in the room by anxiety,
13 irritability, jitteriness, depression, apathy, boredom,
14 or insomnia and sleep issues. Okay. And on the web
15 did you want to --

16 GRAHAM: The top right now is cognitive
17 effects, anxiety and irritability and then flu-like
18 symptoms and the rest are roughly around the same.

19 DR. EGGERS: Okay. So very similar to here.

20 Let's take something -- let's take anxiety and
21 in here who -- for someone who picked that, can you
22 explain that feeling to us? Right there. Okay. We'll

1 go with the microphone.

2 ANONYMOUS: It feels like -- like if you're
3 going to get it, I mean if you're going to get the drug
4 or something like that.

5 DR. EGGERS: Okay. So it's anxiety overall,
6 yeah.

7 ANONYMOUS: Overall, yeah.

8 DR. EGGERS: Overall. Okay. Anyone else?
9 Okay. So the -- in the cap?

10 ANONYMOUS: Yeah, it's like if you don't have
11 the money you can go through anxiety and then the
12 jittery part is like when like somebody described
13 feeling something crawling through your skin and it's
14 just -- and being irritable.

15 DR. EGGERS: Okay.

16 ANONYMOUS: It's just -- it's overwhelming.

17 DR. EGGERS: So you're really tying in the --
18 how difficult it is to tease apart feelings you get
19 about when am I going to have -- when am I going to
20 have the next chance to use versus the feelings that
21 you get that are symptoms that's probably hard to tease
22 out, it sounds like.

1 ANONYMOUS: No. It's more about like being
2 scared that you're not going to get it and that brings
3 the anxiety in because you don't want to be sick.

4 DR. EGGERS: Okay. Okay. We'll go here and
5 then we have to --

6 ANONYMOUS: You can also have anxiety attack -
7 -

8 DR. EGGERS: Okay.

9 ANONYMOUS: -- like a bomb, bombing. You know
10 what I mean?

11 DR. EGGERS: Yeah, yeah.

12 ANONYMOUS: Because I scared a lady half to
13 death on a train one day.

14 DR. EGGERS: Okay.

15 ANONYMOUS: And all what I spit out was
16 (inaudible).

17 DR. EGGERS: Okay. Uh-huh.

18 ANONYMOUS: And it was shaking.

19 DR. EGGERS: Uh-huh.

20 ANONYMOUS: Scared her half to death.

21 DR. EGGERS: Yeah.

22 ANONYMOUS: She thought I was dying.

1 DR. EGGERS: So there are times when a panic
2 attack can happen that goes beyond just --

3 ANONYMOUS: Right.

4 DR. EGGERS: -- the anxiety you feel every
5 day. I think we have Mitra who has a question.

6 DR. AHADPOUR: Just some clarification. So
7 you have the anxiety because you're thinking of --
8 maybe because the question says reducing use. So you
9 have that anxiety that you want to get the opioids.
10 What about anxiety before the opioids? Did you have
11 anxiety before using the opioids and you kind of self-
12 medicated yourself with the opioids?

13 DR. EGGERS: Okay. Getting a lot of head
14 nods. Anyone to explain and we'll go here and then
15 we'll go back in the back.

16 ANONYMOUS: So my experiences is that prior to
17 getting clean and staying clean, those instances of
18 trying to stop and stay stopped, you handle anxiety
19 because you're familiar with the feeling of anxiety
20 that, you know, when you're starting a new job, when
21 life is good, when life -- you know, you're doing
22 different things, you feel this and experience anxiety

1 in your body.

2 However for the addict mind it is resemblance
3 of withdrawal symptoms. So even though I may not be
4 drug sick, even though I may have not used in 30, 60,
5 90 days because my body does not understand -- well,
6 rather my mind does not understand that my body will
7 experience anxiety the same way I experience withdrawal
8 my mind will tell my body that I need drugs to manage
9 the anxiety that I'm feeling which leads me back to
10 using. So it's the miscommunication between mind and
11 body because habitually when I feel that it's
12 associated with the fact that I'm about to go
13 (inaudible). But when you're not using for long
14 periods of time and you feel those anxiety feelings or
15 you feel just the irritability, the jitteriness, the
16 mind associates it with the fact that I'm in withdrawal
17 and because my mind can be stronger than my body it
18 will direct me to go use when that's not even my
19 purpose of going outside that day.

20 DR. EGGERS: Thank you so much. Thank you.
21 We'll go back there.

22 ANONYMOUS: Yeah, I would kind of characterize

1 my anxiety as just the symptom of the underlying trauma
2 that I experience which is actually something I'm a
3 little shocked that I haven't heard yet as trauma being
4 a huge predictor of developing a substance use disorder
5 particularly an opioid use disorder and that's my
6 experience. As 16 years old I was physically assaulted
7 by older man. And when I was 23 years old I was
8 assaulted while under police custody by court officers
9 of the Nassau County prison system. So my anxiety is
10 directly associated with the trauma that I experienced
11 and I constantly relied on self-medication through
12 cannabis to deal with that anxiety successfully but
13 without developing any other health coping mechanisms
14 my substance experimentation gravitated towards opioids
15 eventually which were far better at alleviating anxiety
16 in the short-term than cannabis was but once they
17 stopped working they stopped working and that's all I
18 wanted to continue to do, was figure out a way to get
19 them to work again.

20 DR. EGGERS: Thank you. You're making this
21 very important point about how complex the issue. If
22 you can address your OUD there may have been a reason

1 that you had OUD and so the needing to understand what
2 is what and address both of those at the same time.

3 Okay. We have lots of hands up. We're going
4 to go here and then -- and then I want to -- if there
5 are people on the phone who would like to talk about a
6 health effect that you haven't heard much about or your
7 experience -- or it's really, really bothersome to you,
8 please feel free to join the phone. There's some
9 instructions on the webcast. Okay.

10 SHARON: Okay. This is Sharon again. I had
11 anxiety as a child. I was shy as a child which when I
12 got like about 14 it led me to alcohol because the
13 alcohol like kept me from being shy, I became more
14 outgoing. And the first time I tried heroin I didn't
15 graduate from one to the other, I went from alcohol to
16 heroin and the heroin seem to have done a better job
17 with my being, you know, shy, you know, I became the
18 life of the party.

19 So I tended to stick with that because I
20 didn't like being withdrawn, you know, and hating to go
21 out of the house not wanting to be around people,
22 feeling that everybody was looking at me. So the

1 heroin took care of that.

2 DR. EGGERS: Thank you. Thank you. Okay. Do
3 we have anyone on the phone?

4 GRAHAM: We are showing no comments from the
5 phone line.

6 DR. EGGERS: Okay. If you want to come on the
7 phone then just dial in. There was some -- okay, in
8 the back there, Shanon. Thanks.

9 ANONYMOUS: So I was diagnosed with depression
10 and anxiety before my drug use and that manifested into
11 eating disorder which then manifested into opioid for
12 me. So my anxiety before was a black hole and then the
13 using and also the withdrawal exacerbated that issue as
14 well. So anxiety for me is like a deep, dark hole,
15 wanting of something I can't quite understand and then
16 nothing in this world would satiate that anxiety, and
17 trying to reach for something but wanting nothing to do
18 with the process of fixing it. So, yeah, that's about
19 -- that's about anxiety for me.

20 DR. EGGERS: Thanks. Any other symptoms that
21 you want to follow-up on before -- yeah, go ahead,
22 Elektra.

1 DR. PAPADOPOLOUS: I just wanted to hear a
2 little bit more about the insomnia or sleep issues
3 peoples experience and whether that's related to any
4 other symptoms, perhaps anxiety, just, you know.

5 DR. EGGERS: Okay. So is your fatigue or
6 sleep issue a symptom of something else that keeps you
7 up at night or other thing?

8 DR. PAPADOPOLOUS: Well, it was sort of -- it
9 was kind of a chicken and the egg problem, is sleep
10 related to the anxiety and then the fatigue after that.

11 DR. EGGERS: Okay. Any comment? We'll go
12 back there.

13 ANONYMOUS: As far as anxiety, as a survivor
14 from being molested at a young age and I suffered with
15 anxiety and then couldn't figure out what I wanted to
16 do in life, I was dealing with death and using drugs
17 was the anxiety got ever worse. I didn't even know I
18 was going through that till I was diagnosed from a
19 doctor, you know. So relating to what the young lady
20 over there said if I'm a child, you know, just you grow
21 up with it. You don't know how to feel, what you're
22 feeling, you know, you just don't know.

1 DR. EGGERS: Yes, over here. Shanon?

2 ANONYMOUS: I think -- been thinking about
3 reducing or abstaining from opioids. My mind goes to
4 having to think about, you know, the trauma that I went
5 into. So, you know, not being able to use is meaning
6 having to -- having my life in my face again and in the
7 past experienced maybe PTSD or something, depression,
8 boredom when I'm not going to be able to have drugs I'm
9 just going to have to really be back into with the
10 trauma.

11 DR. EGGERS: Thank you. Thanks. Okay. So I
12 do need to take a time check because we are at 12:00
13 o'clock. Can I go 15 minutes into lunch? We'll let
14 lunch go a couple minutes after, is that okay? Are we
15 -- okay. This is an important topic.

16 All right. We're going to take a few more and
17 then I do want to get to another polling question that
18 very important. So we'll go here, we'll go with you
19 and then you and then we'll --

20 STEVEN: Yes, how are you doing? My name is
21 Steven (phonetic). During my drug use sleeping was
22 hard for me. I would have naps. I wouldn't sleep. It

1 will be more so as naps and that led me having more
2 anxiety.

3 DR. EGGERS: Okay.

4 ANONYMOUS: You know. So it was very, very
5 hard for me because I just like, I could not sleep,
6 right now I still suffer from it.

7 DR. EGGERS: Okay.

8 ANONYMOUS: I cannot sleep. I had to go
9 through various tests, you know, trying to find out why
10 couldn't I sleep a whole night. I take naps, I take
11 15, 20-minute naps.

12 DR. EGGERS: Okay.

13 ANONYMOUS: Every night.

14 DR. EGGERS: Short naps. Yeah. Okay.

15 ANONYMOUS: Short naps.

16 DR. EGGERS: Okay. Right here. And then I
17 understand we have someone on the phone -- two people
18 on the phone. Okay.

19 YVONNE: Good morning. Yvonne. You asked
20 about the anxiety and how it effects the sleepness. I
21 used to be anxious and also have the racing thoughts,
22 so that would keep me awoke with my thoughts racing on

1 back then what's going to happen, what I'm going to
2 have to do, all that kept me -- the thoughts wouldn't
3 stop. So that's how my anxiety affected my sleepness.

4 DR. EGGERS: Thank you very much. We have on
5 the phone -- operator, can we have a caller, please?

6 GRAHAM: Our first caller is caller number
7 one. Your line is now open.

8 DR. EGGERS: Thanks.

9 ANONYMOUS: Yes, thank you for the opportunity
10 to share. I just wanted to say the protracted
11 withdrawals, the long-term withdrawals are the things
12 that made it so hard for me and even now after being on
13 methadone and then Suboxone for years. I reducing my
14 dose I still have issues, but like I detoxed a bunch of
15 different times. And I could get through that first
16 week of being sick, but I couldn't function the longest
17 ever when it was like 5 months and still I will have
18 nights of what I call are skin crawls where you can't
19 lay still, you never mind, go to sleep, your body just
20 jerks and, you know, anxiety, anxiety attacks. You
21 feel like a cat on a hot tin roof and it went on and on
22 and it never did get better. I know some people get

1 off of opioids and apparently they do get better but I
2 had to go in medically assisted treatment to get my
3 life back.

4 DR. EGGERS: Thank you very much. Thank you.
5 And we have one more caller. Operator?

6 GRAHAM: Next comment comes from caller number
7 two. Your line is now open.

8 GERI: Hi, my name is Geri Lynn Utter, I am
9 actually a doctor of clinical psychology and, I guess,
10 a caregiver. My mother has suffered with opioid use
11 disorder for 20 years. So just to kind of, you know,
12 in listening to everything, I feel like I am listening
13 to my mom and then as a professional, somebody that
14 specializes in addiction, I can just really empathize
15 and what I just wanted to kind of reiterate as far as
16 the comorbidity with posttraumatic stress disorder,
17 anxiety, it's something that we see very commonly,
18 depression.

19 And, you know, when you have years of drug
20 abuse I just kind of want to reiterate to you that
21 there is actual brain chemistry that changes and the
22 way that your brain function, functions changes. So

1 it's not a matter of, you know, of will power and, you
2 know, polling yourself up your bootstrap, this is an
3 actual brain disease. So everything that you are
4 talking about as far as trauma, anxiety, depression,
5 it's all symptomatic and reflective of the disease of
6 addiction. So medication-assisted treatment somebody
7 mentioned and if it works for you, if Buprenorphine or
8 methadone, if it's something that works for you and
9 helps to manage, you know, cravings, anxiety, then, you
10 know, it's something that's actually helping with your
11 brain neural transmission.

12 So, you know, just to kind of echo what folks
13 are saying, I just want you to know that, you know, as
14 somebody in the field, but also as a child of somebody
15 who is addicted, I empathize with you and I think, you
16 know, from a care standpoint, you know, we can't just
17 look at opioid use disorder linearly we have to look at
18 all of the mental health issues that come on top of
19 either being addicted for many years or using opioids
20 to self-medicate depression, anxiety and trauma.

21 So when you do enter into treatment, you know,
22 opioid use disorder is just one thing that you are

1 going to work on, you are going to have to really work
2 on everything in order to feel whole or whatever your
3 normal is again

4 DR. EGGERS: Yeah. Thank you.

5 GERI: So I just kind of wanted to share that
6 and thank everybody here today for participating
7 because I really empathize and understand your pains.

8 DR. EGGERS: Thank you so much. There were a
9 lot of head nods in the room, you know, you can't see
10 us. It's going to be a nice transition to our
11 discussion on treatment approaches and what you look
12 for out of treatments in the afternoon. I do want to
13 make sure that we get to one more polling question
14 because that's important. It's not thinking so much
15 about symptoms, but about how these -- what OUD has,
16 that there are bigger impacts. We have -- yeah, just
17 we will take one question -- one comment and then we
18 will -- you can -- we will do the polling questions.

19 ANONYMOUS: To be in recovery, it didn't take
20 us overnight to get like this, so when you get cleaned
21 it's going to take you some time --

22 DR. EGGERS: Yes, yes.

1 ANONYMOUS: -- to get the brain back and that
2 normal feeling because some of us don't even know what
3 normal feels like.

4 DR. EGGERS: That's right.

5 ANONYMOUS: Because we was polluted with drugs
6 for many years and I say that because with me when I
7 got cleaned a lot of health issues fell into play.

8 DR. EGGERS: Yeah.

9 ANONYMOUS: They were there all along, but
10 self-medicating --

11 DR. EGGERS: Yes, thank you.

12 ANONYMOUS: And sleeping is one other thing
13 you go through.

14 DR. EGGERS: Okay. Thank you so much for
15 that. So then transitioning into these impacts on your
16 or your loved ones daily life, okay, you can chose up
17 to three things. So this is what's the most -- what
18 were the -- where are the biggest impacts for you,
19 okay. A, your ability to carry out important
20 activities like go to school, work, do hobbies that are
21 really important to you, be on the sports teams. B,
22 ability to care for yourself or your family. C, having

1 days when I am barely able to function at all. D,
2 concerns about risks to -- risks to safety of self or
3 others. E, impact on relationships with family and
4 friends. F, stigma or discrimination. G, worry about
5 the future such as worrying about relapse or overdose
6 or other things such as your family. H, emotional
7 impacts such as self-esteem, self-identity or I, other
8 impacts not mentioned. This is a hard question and I
9 promise, we will stop and have a break in lunch after -
10 - after this.

11 You have a question? There were -- let's just
12 see what the polling questions come and then I will
13 come to you. Okay. So let's -- is anyone still
14 working, still thinking? Okay. Yeah, okay, let's give
15 a few more minutes.

16 ANDREW: Okay. Can I share something?

17 DR. EGGERS: Yeah, go ahead, Andrew.

18 ANDREW: So it's really interesting that
19 trauma came up and I love that it did, I have this, I
20 don't know if it's my own or if it's just -- if it came
21 from somewhere else, but I just wildly, you know,
22 radical idea that recovery actually starts with the use

1 posttraumatic event and you hear this a lot, you know,
2 sexual abuse, physical abuse or some traumatic event
3 that kicks off, seeking a relief from that.

4 The chemistry degree, my capstone I actually
5 did around the brain chemistry of trauma and how it has
6 very causal links to, you know, neurodegenerative
7 diseases such as ALS, Parkinson's, Alzheimer's, but
8 also a lot of substance use depression, anxiety, I was
9 really curious to see how that same biological process
10 is playing out in other ways in our body and come to
11 find out that your skin cells actually react to the
12 sunlight in a similar fashion.

13 The UV light breaks apart the skin cells
14 creating free radical oxidatives that go on and just
15 kind of bond with anything and react with anything in
16 its path and creating a lot of nasty toxic things
17 including sunburns. And if you get repeated
18 overexposure, cancers, skin cancers. Trauma is in
19 short the sunburn of the brain.

20 DR. EGGERS: Okay.

21 ANDREW: And we are finding our sunscreen in
22 drugs and alcohol, it just so happens that it's not an

1 effective or sustainable, you know, solution. And so
2 we are really like I really hope we can tease out some,
3 you know, productive and positive sunscreens for this
4 brain trauma --

5 DR. EGGERS: Thank you for the analogy.

6 ANDREW: Thank you.

7 DR. EGGERS: Thank you. Okay. So thinking
8 about the big impacts, it's everything, you have
9 identified everything and nothing stands out more than
10 -- it sounds like it would be -- this was probably a
11 very difficult question, so we appreciate you answering
12 it. But the emotional impacts, the stigma or
13 discrimination which we heard about, the ability to
14 function, having days where you are barely able to
15 function at all, let alone go to work. I would like to
16 hear what the effects are, the impacts on the phone
17 are.

18 GRAHAM: Yeah, so very wide dispersion of
19 results, we have about 46 percent for ability to carry
20 out important activities, 42 percent with having days
21 not being able to function, 50 percent family and
22 friends and then about 30 to 35 percent for stigma,

1 worry about the future and emotional impacts.

2 DR. EGGERS: Okay. So I want to -- I am going
3 to close with one question which is it surprises me
4 that, B, ability to care for myself or family was not
5 as high of a choice for the folks in the room. Does
6 anyone have, from your experience, a possible reason
7 why you didn't put that -- you put other things, but
8 not that one as your top. We'll go back there and we
9 will take one more and then we'll close up for lunch.
10 Go ahead.

11 ANONYMOUS: Particularly these other things
12 were a little more salient, I mean, I wouldn't deny
13 that the ability to care for myself and family is an
14 important thing, but in particular I identified stigma
15 as the most important thing because quite frankly
16 opioid use disorder is not going to make a tremendous
17 progress towards a solution until we remove the
18 criminal justice component from it. Sure there are
19 crimes that are committed during the process, but if by
20 definition certain characteristics of this disorder are
21 inherently criminal, that's never going to end without
22 that criminal justice component removed.

1 DR. EGGERS: Okay. Thank you. Good point,
2 good point. We will go back here and then we will take
3 two more because you had your hand up and then we will
4 go to you and then we will -- and then we will have to
5 go to lunch.

6 ANONYMOUS: I am designing a program to
7 educate judges --

8 DR. EGGERS: Okay.

9 ANONYMOUS: -- about opioid use and so I
10 would be interested if you can have a chance to ask the
11 people in this room who have used or are using opioids
12 whether they ever had experience with the law, whether
13 -- an arrest for example.

14 DR. EGGERS: Okay. Can we do this, just to
15 show a hands, are you comfortable raising your hands if
16 you have had an experience with the law?

17 AMANDA: And you should come talk to me when
18 you are done this because, yes, you should come talk to
19 me.

20 DR. EGGERS: Okay. Okay. All right. So we
21 are going to move on. We have -- we're going to go
22 with you and then we'll close with you, go ahead.

1 Right here the -- no, with the dark shirt on.

2 ANONYMOUS: Yeah, my question is the ability
3 to care for my family when actually watching my mom
4 trying to raise nine kids by herself being abused by my
5 father and that led me to go out and sell drugs and
6 being in prison, so.

7 DR. EGGERS: Okay. All right. So that's a
8 different perspective on being able to take care of
9 yourself and family. We're going to have -- we're
10 going to go there.

11 ANONYMOUS: No, I think you are absolutely
12 right, you know, when you said that, you are right that
13 it should be A, but for me it was not being able to
14 have meaningful relationships. But maybe it's part of
15 the opioid use disorder disease that, my brain disease
16 doesn't even make me think, I need to take care of
17 myself, you know what I mean, I am just wondering if
18 that's a part of it, that it should be A, but it's not,
19 you know.

20 DR. EGGERS: Well, there was no judgment in my
21 question, it was just an observation. Okay. Let's
22 see. Since we have heard from, I am going to go to

1 this gentleman, we haven't heard from and then we'll go
2 summarize anything on the webcast.

3 WAYNE: My name Wayne. The reason why I had
4 the ability to consume, I was addicted to dope. I let
5 my mother, I gave her the assets, my bank account, so -
6 -

7 DR. EGGERS: Yeah, yeah, thank you. Yes.
8 Okay. So we have one question, then we'll summarize
9 one quick follow up.

10 DR. AHADPOUR: So one quick question before
11 lunch. Worry about overdose, can I see a show of hands
12 who are worried, I mean, just individuals, caregivers
13 that are worried about overdose.

14 DR. EGGERS: Even if you are in recovery.
15 Okay.

16 DR. AHADPOUR: And any solutions for it. May
17 be afterwards.

18 DR. EGGERS: Let's -- we can see if we can
19 come afterwards. Here is what I wanted -- there is a
20 couple of things, if you feel comfortable on the
21 webcast typing this in over the lunch time or some time
22 or if you feel comfortable submitting comments to our

1 public website, what we haven't talked about was
2 relapse and your experiences with it and what -- maybe
3 we can get to that a little bit of that this afternoon.
4 We also haven't talked about OUD during pregnancy. If
5 you have experiences or perspectives on that, please
6 share those. And then what worries you most about
7 living, I think we've gotten through that in the
8 conversation. So summary of the webcast, please.

9 GRAHAM: So we heard several people talking
10 about why they didn't chose ability to care for myself
11 or family, they said they had other things they
12 consider more important such as their worries about
13 work and staying employed. Other people said that they
14 just chose options that they felt actually defined
15 caring for self and family such as days not being able
16 to function or inability to go to school or work and
17 for a lot of other people talking about some of the
18 trauma that they had experienced and what they started
19 using opioids for to try and deal with it and then
20 other people also echoing some of the incidents with
21 the law and other types of issues like that.

22 DR. EGGERS: Okay. Thank you. You can keep

1 the webcast coming in. We're going to close for lunch
2 now. We will give you the full hour. And so we will
3 start promptly at 1:15 and we'll make up time in the
4 afternoon.

5 First though, can I have the -- everyone give
6 a round of applause for just fantastic input today this
7 morning.

8 (Applause)

9 DR. EGGERS: Thank you very much. If you have
10 any questions, come find Pujita or myself and we can
11 answer them. Thank you.

12 LUNCH

13 AFTERNOON WELCOME

14 DR. EGGERS: Okay. All right. Thank you
15 everyone for a fantastic morning discussion that
16 covered a lot of issues that are very difficult to talk
17 about and especially when we say you have got an hour
18 go. So I want to thank you for the rich insight you
19 gave at that meeting, for that discussion.

20 I also wanted to point out and just as a
21 reminder that we did talk about sensitive issues such
22 as suicide attempts and suicide thinking and I just

1 want to remind everyone that there is help, seek help
2 if you need it, this is the suicide prevention
3 lifeline, it is very important. And I also wanted to
4 remind you about sending comments to the public docket,
5 to the website, again you can submit without putting
6 any names associated with it or any -- you don't have
7 to give us any personal information about yourself.

8 But you have more to say and I know this about
9 the first topic. And if you are on the webcast, we
10 know you have more to say about that. So please
11 consider doing that. You have until June 18. Okay.

12 PANEL #2 DISCUSSION ON TOPIC 2: CURRENT APPROACHES
13 TO TREATMENT OF OUD

14 DR. EGGERS: And now we are going to move into
15 a discussion on current approaches to treating opioid
16 use disorder. And that is there are some -- there are
17 the medications that we will talk about, we will also
18 talk about other treatment or therapies that you do and
19 how they work together. We won't be able to get into
20 every aspect of the management of OUD. We will be
21 focusing primarily on the medical treatments and we
22 would like to know how well those are working for you

1 and what the biggest problems you faced in using these
2 treatments.

3 We'd also hope to get out of this afternoon
4 what you find to be the most effective in helping to
5 manage your OUD, again with a lot of focus on medical
6 treatments and the aspects of medical treatments but
7 also other things knowing that it is a very -- that it
8 takes a village to help. And what you think about when
9 you are making decisions about seeking out or using
10 treatments or not using treatments.

11 I understand we have particularly some people
12 on the webcast who are not currently utilizing
13 treatments and so if you are on the webcast listening,
14 please type in -- type in your thoughts as we get to
15 those.

16 I am going to ask the panelists to come up,
17 Paul, Carol, Jan and David is on the phone. Oh yes, I
18 am sorry, and Daniel, I was reading David twice, so.
19 You can make your way up, it's the same setup for topic
20 two. We do have a break at around 2:20 and I want to
21 say one other thing that I am -- that I imagine it
22 doesn't get set off in an FDA. I want to -- I want to

1 apologize, we did not inform you about the no smoking
2 policy here.

3 So for those of you who needed to, we are
4 surprised that you had to walk all the way down to the
5 stop sign -- stop lights, I apologize that, A, that we
6 didn't inform you and, B, that that street is so long.
7 So I joke a little bit, but I do apologize for not
8 informing you of that in advance. We appreciate your
9 patience with that. Okay.

10 We are going to actually start with David who
11 is on the phone with the first panel of comments. And
12 so operator, can we have David?

13 GRAHAM: Your line is open.

14 DAVID: Hello.

15 DR. EGGERS: Hi David.

16 DAVID: Hi, how are you?

17 DR. EGGERS: Good, thank you. I am glad you
18 are able to participate on the phone. Again you can't
19 see, we know you can't see the room, but it is -- there
20 are many people in here and they show their agreement
21 with you by nodding their heads which you can't see,
22 but we can see it and so we know that what folks who

1 are saying on the phone is resonating with folks in the
2 room, so. So with that please go ahead.

3 DAVID: All right. Great. And I wanted to
4 say a big hello to the IBR Reach folks from Baltimore,
5 I am sorry I couldn't be with you guys. I took some
6 sushi that was on sale yesterday and I am paying for it
7 today. So my apologies, but nevertheless I still felt
8 it was very important that I would be able to speak and
9 my gratitude to you, Sara, also for setting this up and
10 letting me spent a couple of minutes talking about
11 myself.

12 Basically nothing really special as far as
13 drug use, I enjoyed using drugs as a teenager, mainly
14 social, you know, social drug, I was never really into
15 heavy drugs. So amongst my friends, we enjoyed smoking
16 pot, we did LSD and MDMA, you know, stuff like that,
17 mushrooms and just one day somebody suggested to snort
18 some heroin and I never heard about snorting heroin,
19 the only times I thought about heroin was, you know,
20 when you saw it in the movies, people injecting it and
21 dying.

22 So I -- in my mind I never thought it would be

1 possible, but nevertheless I figured, well, it can't be
2 that bad if you are only snorting it. So I gave it a
3 try and, you know, truth be told, I didn't like it, I
4 vomited, I had a real bad reaction to it, but, you
5 know, as much as I didn't like it for some reason the
6 next time it came around I tried it again and, you
7 know, off went the boat, so to speak, and it lead to me
8 to places I have never expected to be in my life and,
9 you know, life was very difficult for me at that point.

10 I lost -- most of my family members turned
11 their backs on me, most of the friends that I so called
12 had, they just, you know, they had wanted nothing to do
13 with me and I ended up being homeless in Baltimore
14 panhandling, living on a mattress at an apartment
15 complex and it was very difficult also for me to get
16 syringes.

17 Every time I went to the pharmacy, they
18 refused to sell syringes to me, you know, they played
19 games with me, well, what do you need them for, for
20 diabetes, well, what kind of insulin do you take, you
21 know. So there would always be some trick questions
22 that I didn't know the answer to and it was very

1 difficult for me to get syringes.

2 So one thing led to another and I heard about
3 the needle exchange program they had in Baltimore.
4 There was a van that would go around in the city and
5 they would basically take your old syringes and give
6 you clean ones. And so I signed up and I was about 22
7 at that time and one day I came to pick up new needles
8 and the guys there on the van said, listen, there is a
9 mayor's initiative program and it's a program for folks
10 that, you know, are drugs users that are trying to get
11 some help. If you like the next time we arrive,
12 whoever is first in line we'll give that treatment
13 blotched (phonetic). Excuse me.

14 And so I figured, you know, let's give it a
15 shot, I tried detox before, I tried rehabs, I tried 12
16 Step programs, I could never get clean for longer than
17 may be a couple of weeks. I would constantly relapse
18 and no matter if it was jail or hospitals, I mean,
19 there were plenty of times where, you know, I ran out
20 of drugs and money I will just go to the ER and tell
21 them that I was -- that I was suicidal because I knew
22 that they would take me in and at least give me some

1 kind of medicine, so I won't be sick.

2 So I had to manipulate my way in order to be
3 able to just receive some sort of treatment so I won't
4 be on the street going through withdrawals. And so
5 sure enough that day I came and they gave me a
6 treatment slot and I went to a program, it was a van, a
7 big mobile van that would drive around in the city and
8 they would dispense LAAM, for folks that don't know
9 LAAM is similar to methadone but instead of taking it
10 every day you would only take it three times a week.

11 And so, you know, I decided, sure, why not, so
12 I started taking the medication, I kept using drugs and
13 after about a month or two when I was -- decided to use
14 I didn't feel it anymore. When I bought the heroin and
15 I injected, I just had no euphoric rush whatsoever.
16 And so I guess the medication kicked in and it started
17 working and let's see.

18 March of 2000 was the last time that I did any
19 kind of illegal substances after that. And the
20 medication just started working and, you know, I would
21 go to the program, I would comply with their rules and
22 surely enough I was able to get my life back in order.

1 And in about 2003 they decided to switch most of the
2 folks to methadone. I guess, some folks were having
3 issues with the LAAM, with having QTs and issues with
4 their heart and we would have to get regular EKGs and I
5 was always fine with it, but I guess, they decided to
6 take it offline and just switch everybody to methadone.
7 So, you know, it was no problem for me, the dosage was
8 fine and, you know, after a while I was able to earn
9 (inaudible) and at this point, you know, around 2010 I
10 qualified for a monthly take home where they will give
11 me a methadone hydrochloride tablets for suspension
12 and, you know, I would take those and just, you know,
13 what they do is instead of the liquid you actually have
14 to mix it with water and you would just drink it and it
15 has been fine, I mean, you know, I was able to get my
16 life in order, I was able to arrest the cravings and
17 the compulsiveness around the disease and the chasing
18 and, you know, the insanity of it.

19 And, you know, life was slowly but surely
20 getting back to normal. I was able to go back to
21 school. I was able to expunge my criminal record which
22 I never thought would be possible and to get my U.S.

1 citizenship, so just the stuff that I prayed for and
2 thankful for, you know. So just the thing is with the
3 medication, you know, of course with methadone like any
4 medicine it works great, but, you know, there are
5 issues with the two, I have to take other medications
6 because certainly with the methadone there are some
7 side-effects that I have, some weight gain, certainly
8 the constipation, the low testosterone and so, you
9 know, I was prescribed Constulose for the constipation,
10 AndroGel for the low testosterone, Glycopyrrolate for
11 the sweating, you know, I am sure a folks they know.

12 When you are on methadone you sweat a lot and
13 it can -- it can come out of nowhere, you know, it
14 doesn't have to be even hot outside, you could just be
15 sitting in a normal room and then out of nowhere you
16 just start sweating really hard. So, you know, there
17 are certainly some side-effects that come with it, but
18 it's like with any medication, you know.

19 So for sure if there are other stuff in the
20 future that, you know, would, you know, would benefit
21 me in as far as switching to another medication, I
22 would be very interested to, you know, to volunteer and

1 see if there are other stuff, you know, other
2 treatments available. But as far as the dosage goes,
3 you know, my sensitivity is extremely low, you know, I
4 have tried to taper off methadone before and I was
5 always unsuccessful where it was just -- the withdrawal
6 symptoms were extremely high and my tolerance was very
7 low.

8 So, you know, some people say you might have
9 to stay on it for the rest of your life which, you
10 know, I guess, in terms of living life, yeah, you know,
11 my life is definitely better, but for sure I would like
12 a life without any kind of medication in the future,
13 that will be the ideal situation. So I am not going to
14 take up more time, but again, you know, the medication
15 definitely saved my life.

16 DR. EGGERS: Thank you.

17 DAVID: And I probably wouldn't be here
18 without it, but, you know, for sure I would be very
19 interested in future discoveries and anything I can do
20 to volunteer. You know, if there is anything that
21 could be gained from the years that I have been on this
22 medication I would love to share it with the world. So

1 thank you.

2 DR. EGGERS: Okay. Thank you, David. Thank
3 you.

4 (Applause)

5 DR. EGGERS: Thank you very much. We are so
6 thankful for you sharing your story. And so now we are
7 going to go down the line and we will go with Paul.

8 PAUL: Okay. Hi, my name is Paul REDACTED, I
9 am a 54 year old man from Boston, Massachusetts and I
10 have substance use disorder and I kind of thinking back
11 when I was preparing this I thought about when did I
12 know that I liked opioids and I think I was 12 years
13 old and I had some -- the teeth worked on and I can
14 remember sitting at home and liking the feeling and
15 watching TV being on an opioid and I remember taking
16 the whole prescription, you know, not all the same day,
17 but so 12 years old and that's when I -- well, I really
18 like the way this feels, kind of tune out in the world.
19 So go through life and went to college and went to high
20 school and came out as a gay man and then when I was 32
21 years old I had a surgery for gynecomastia which is
22 breast tissue enlargement and so after that I was

1 treated for the pain, the acute pain and then I was
2 like, this is just too good to give up and I was
3 treated for that surgery for three years for the pain
4 and at the end I had this doctor writing me
5 prescriptions for injectable Demerol and getting
6 Dilaudid and Oxycodone and all the rest of it, and
7 that's when I really just knew that I just needed this
8 medication, so I would doctor shop and even to the
9 point of everything, you know, even trying heroin and I
10 was injecting medicine.

11 If it wasn't for the needle exchange van in
12 our neighborhood, I would have had HIV or hepatitis C,
13 but thank God, you know, I sought out that. So then I
14 -- and I still wanted, you know, at this point it had
15 been, you know, 3 years and I lost my family. I still
16 have my job. I work as a social worker. I took FMLA.
17 I think that I thought I was dying of something, they
18 had no idea why I never came to work, but I was almost
19 fired many times. So I would go to detoxes and I went
20 to at least 10 different detoxes and then I would come
21 home and then -- and then relapse again and then
22 relapse and relapse and relapse and then I would do 90

1 days programs, 90 meetings in 90 days and then relapse.

2 And then finally a doctor said to me, well,
3 you know, you are just too hard, we can't figure you
4 out, maybe you need to go into the world of liquid
5 handcuffs and go on to a methadone treatment and I did.
6 And it was really hard though because I made an
7 appointment, took 8 weeks to get the appointment, okay,
8 and then I get there and I only had a check or credit
9 card or cash, they needed a money order, so they sent
10 me off to the bank. By the time I got back my
11 appointment was over. They said, well, you have used
12 up your time, you need to come back in another 8 weeks.

13 So then I came back in 8 weeks and they said,
14 you need to have a positive opioid, so I think, what, I
15 had made it through these 8 weeks and I had to go out
16 and score heroin in order to get into a methadone
17 program. So I scored the heroin, then got an overdose
18 and I got into a methadone program and all of a sudden
19 they say, if we know what I had they are doing take
20 homes and I was -- I was going to work and I would go
21 to Christmas and Thanksgiving and had my family back,
22 meaningful relationships and it was just incredible and

1 then I did have some of the side effects that David
2 mentioned, you know, the sweating and sexual
3 dysfunction. And I said, you know what, in 2003,
4 buprenorphine came on the market. And I said, "I am
5 going to try this." So I got into buprenorphine. And
6 it's been pretty good since then. I went on to a
7 pretty high dose of that. I mean, not high dose. I am
8 on 24 milligrams. And now I am on 16 milligrams. And
9 it's an easier drug to manage. I think the hardest
10 part of being on methadone was going to the treatment
11 programs. They are always in bad neighborhoods. You
12 couldn't talk to people. What kind of a medical
13 treatment do you have to leave as soon as you get it?
14 Well, if you hug somebody, you could lose your take-
15 homes or if you talk to other people -- I mean, it
16 didn't seem like it was a part of any kind of
17 medication system or a medical system that was
18 integrated.

19 Now, I see a doctor in a primary care setting.
20 The people sitting in the chair next to me are there
21 for diabetes and hypertension. You know it's my most
22 scary moment on methadone was going into the clinics to

1 pick up my take-homes that someone might jump me
2 because they might be new in recovery, and want to take
3 my take-homes.

4 So now, nobody knows why I am at the doctor's
5 office to see my doctor, who I see once a month. And
6 they have a nurse model. I go to office based opioid
7 program in Boston. And is so lucky that in Boston, we
8 have such progressive medicine. And we don't have to,
9 you know, go down some dirt road, that's on the way
10 (phonetic) to get your methadone treatment. And I
11 don't mean to trash methadone because it saved my life.
12 It's a wonderful drug. I just think that it's too bad
13 that we have to have it so by itself and not a part of
14 any other part of the system.

15 So I am also want to tell you I am with the
16 National Guidelines for Medication-Assisted Treatment.
17 They actually help me a lot. There's a lot of things
18 online that help me with methadone discussion group
19 that we had like three people, now there's 8,000
20 methadone patients that are on Facebook that help each
21 other out, and if it wasn't for that. So the
22 medication was huge but other biggest piece for me,

1 peer recovery centers. I went to a peer recovery
2 center and meeting other people in recovery and them
3 helping me, in having you know, people in recovery help
4 each other. And I think that really made my recovery
5 strong.

6 And then at the methadone clinic, I know
7 there's one in New York that they do actually have a
8 methadone -- a peer recovery center at the clinic. But
9 most of them, they don't have that. And I think if
10 they had more treatment like that or things like that,
11 you know if they had coaching back then it would have
12 been helpful for me.

13 DR. EGGERS: Any final thoughts as you wrap up
14 on what you'd like to see the future of treatments look
15 like?

16 PAUL: I think that we need to integrate
17 methadone into primary care.

18 DR. EGGERS: Okay.

19 PAUL: And we need to change these
20 regulations. There's just too much autonomy, I mean
21 just whatever the state wants to do, they can do. And
22 some states don't give out any take-homes. And we've

1 got to deal with this stigma thing. If people don't
2 meet people like the people in this room, they are
3 going to not ever accept this form of treatment. They
4 are going to see the people that aren't doing well on
5 methadone and Suboxone and think everyone is passed out
6 in a corner, which isn't true. There are so many of us
7 in recovery, and we are never going to get rid of this
8 stigma until we can go out there and show the face of
9 this. And I know people can do it because it's -- you
10 know that's their own decision and I am not saying that
11 you need to divulge your medical history to people.

12 But I just think that's whatever that'd be my
13 ideal thing is to get rid of this stigma, and not
14 understand why people don't know about this. I met a
15 mom, a couple weeks ago, whose son had died and she
16 never heard of Suboxone. He was in four, 30-day
17 programs, and nobody ever told her that she could have
18 put him on a medication, that would have had the most
19 science base behind it to treat him, and no one,
20 another abstinence-based program. He went home. And
21 she found him dead in his room and she was pissed. So
22 thank you.

1 DR. EGGERS: Thank, Paul.

2 (Applause)

3 DR. EGGERS: Paul, you raised a lot of --

4 SPEAKER: So what are take homes?

5 PAUL: After 90 days, you're allowed to have
6 one take-home. Some states, they let you have a take-
7 home on Sunday; Massachusetts, they don't give you any
8 take-homes. So that means you have to have --

9 DR. EGGERS: So is it you have the medication
10 you can bring.

11 PAUL: Bring home with you. So every day, you
12 have to come and pick it up. I actually was lucky that
13 my methadone clinic was at the police station. So I
14 get to go to the police station every morning. So my
15 neighbors would say, "Why are you at the police station
16 every morning?" It was very confidential, in the
17 parking lots, so we go there. And a -- so a take-home
18 after you have had 90 days. And you know what, the
19 people said they were clean. None of us are dirty. We
20 don't have to say clean. Stop the language.

21 (Applause)

22 PAUL: You know we have a positive year, and

1 we are not dirty people. Whoever made us think we were
2 dirty, all of this has got to stop in order for us to
3 get rid of the stigma. I am sorry, to be so passionate
4 here.

5 DR. EGGERS: You know the issue of stigma
6 underlies everything we are talking about today. And
7 so even though it's going to be hard for medical
8 treatments to address stigma as a clinical benefit --

9 PAUL: Yeah.

10 DR. EGGERS: -- we do recognize the importance
11 of that even if we don't get to delve into it quite as
12 much today. So thank you, Paul.

13 PAUL: Thank you.

14 DR. EGGERS: And I know that others -- let's
15 applaud if you feel the same way about the importance
16 of stigma.

17 (Applause)

18 DR. EGGERS: So there you have driven home
19 that point. Let's move on to Carol to keep the moving
20 -- the meeting moving.

21 CAROL: Great. Hi, everybody. My name is
22 Carol REDACATED and I am woman in long-term recovery.

1 I started using drugs at age 13. I was genetically
2 predisposed to addiction on both sides of my family, as
3 a first generation Irish-American. I started using as
4 a way -- I started using opioids when I was like 18 or
5 19. And I am old, so I will be 58 in May. So just to
6 give you a sense of how things changed in the drug
7 world. I started using opioids as a way to come down
8 off cocaine, when I was I in college. And opioids had
9 a much worst stigma, I think, than they do today on
10 college campuses, where pain pills and heroin is fairly
11 unfortunately not stigmatized. It caused great shame.
12 There were partiers and then there were those junkies,
13 and when I started using heroin, that's sort of I got
14 that stigma.

15 My experience as a person in long-term
16 recovery, a treatment and recovery advocate as part of
17 my job and my career. I have worked and helped startup
18 recovery community organization in Richmond, Virginia.
19 And I am a part of organizations like Young People in
20 Recovery. And a big shout-out to Young People in
21 Recovery across the country who might be listening in
22 online. What I've learned is that there's no wrong

1 door to recovery. And you know my experience is that I
2 was on methadone treatment. Unfortunately, I did not
3 have as positive as an experience back in the early
4 '80s as David has, and maybe Paul. And please don't
5 send me hate mail. I am not grinding on methadone. I
6 am just sharing my story here.

7 For me, I was following a boyfriend who was on
8 a methadone program. It was in a part of town where
9 you could cop other drugs at the same time and kind of
10 learn you know who was doing what to -- I was the --
11 yeah, who was boosting what at places around town to
12 get money to use. And because I looked kind of sweet
13 and innocent like the Campbell's Soup girl, I was the
14 return lady for stolen goods at stores. It was not
15 great recovery pathway for me, just leave it at that.
16 And I had some of the same side-effects from that
17 particular treatment modality as some others have
18 talked about, not really dainty or feminine to be
19 sweating profusely in the summer. And all of your
20 clothes have these big stains all over them. Yeah,
21 it's not lovely.

22 So I also have used medicalized detox and

1 residential treatment twice that use bio-cycle social
2 model for recovery. And today, I manage my recovery
3 using recovery management techniques that include a lot
4 of things. But that can include -- does include 12
5 sub-meetings and active participation. Being an active
6 member of a recover community organization, I give and
7 receive peer supports from other women. I also use
8 counseling. I use antidepressant to manage anxiety.
9 And I use exercise, meditation, yoga, and therapeutic
10 message, all to help manage my recovery.

11 But patience, experience, and the needs about
12 while there is no wrong door to recovery, patience,
13 experience, and their needs about which door works for
14 them and has worked for them, and that they have been
15 exposed to really matters. And I think it's often
16 ignored. One particular pathway appears to get pushed
17 in this country at any particular time rather than kind
18 of creating a climate and incentives for all options to
19 be viable for people, and that it -- they should be
20 accessible, and it should be based on the patient's
21 needs and experience with other treatments.

22 In recognition of the reality, frankly that we

1 don't have data in this country that purpose perfectly
2 matches an individual to the exact intervention that
3 works for them and until we have that, which I hope we
4 do, people ought to be able to choose pathways and not
5 kind of get forced down to one and shamed if that one
6 pathway doesn't work for you.

7 I think outstanding areas in my recovery that
8 I would like help with, whether through drug
9 interventions or devices or other interventions that
10 are still lacking for me are a really good tool for
11 managing stress. You know stress is a trigger. Even
12 with 20 years clean -- 20 years in recovery -- excuse
13 me -- I still don't have stress management down. And
14 it definitely triggers addictive feelings in me.
15 Today, I have co-occurring addictions. And when I
16 first got into recovery, I remember almost being kicked
17 out of a recovery program because I had co-occurring
18 bulimia and eating disorder. And they were like, "Oh,
19 no, no, no we only deal with drugs and alcohol. We are
20 going to have to ask you to leave." And I kind of
21 begged and pleaded my way into staying. But a person
22 with a substance use disorder that shows up in

1 different areas of their life should not be shamed and
2 be told that you get kicked out because you have more
3 than one way that your substance use disorder expresses
4 itself. And it affects areas of the brain, where it's
5 going to show up in different ways. I think the -- it
6 can also show up for me, on like overspending of money.
7 The feeling of wanting more of anything that changes my
8 mood it's quieted down with 20 years of recovery. But
9 it's not been cured. And it impacts my self-esteem
10 because at this age, I think -- well, or this amount of
11 recovery, or I should have this all together by now,
12 right? Like, "Come on, Carol. Get with a program.
13 You're supposed to be like in a better spot."

14 An addiction is a chronic thing.
15 And we have to teach people that, and that not to shame
16 themselves. As I age, managing chronic and acute pain
17 poses challenges for me in my recovery. Clinicians
18 still push opioids on me, despite me revealing my
19 opioid use disorder and are often unwilling to use non-
20 opioid alternatives, and often there aren't, when I've
21 had to get surgery, call me, or tell my husband that I
22 am hysterical about opioids.

1 Healthcare professionals need to discuss an
2 opioid management plan with their patient who self-
3 identifies having an opioid use disorder, and what
4 works for me, and how I do my opioid plan, but I don't
5 think everybody has to do it this way. Because
6 remember, I am hysterical about the way that I manage
7 it. Is that what works for me is having others handle
8 the medication for me or we've had it in my house and
9 not get a little text and go on a treasure hunt every 4
10 hours or whatever prescribed as. Having an
11 accountability partner. For me, I've talked to sponsor
12 about it, but it could be a loved one or a friend or
13 whatever. And I have a plan for the period that I am
14 taking them.

15 And during recent rotator cuff surgery, I had
16 to stay on opioids for two weeks and I could feel
17 myself becoming -- just counting the footsteps of the
18 person managing the medicine and all of that kind of
19 stuff.

20 So quickly as I finish up, just a couple of
21 systemic suggestions perhaps to leave with people, I
22 think the FDA should use a REMS process more

1 aggressively to require -- those they regulate to help
2 with public education campaigns for individuals,
3 families, and communities. I think we should have
4 medical professional and pure education curricula that
5 they do -- already do and are good at and could do more
6 of. I think that they could use REMS for more
7 strategies and use the FDA for more than just like a
8 black box warning on a drug. I think there's a lot
9 more authority there that could be used.

10 I think price should be looked at for MAT to
11 treat addictions. And in particular if you're going to
12 recommend non-opioid pain alternatives, make sure
13 there's actually insurance reimbursement and coverage
14 of them. Because a lot of times, people will say,
15 "Yes, of course." Like go get the such and such. And
16 I will try to get Toradol and my plan will say, it's
17 not covered. So that doesn't make sense.

18 DR. EGGERS: Any final thoughts, final words?

19 CAROL: Yeah. I think that there is also
20 workforce shortage. And while this isn't necessarily
21 in the FDA's purview, I think that people have to
22 realize that our people who treat addiction don't get

1 reimbursed like other chronic medical conditions. And
2 that is something that payers and others in our
3 community can and should fix, especially since the
4 government is one of the biggest payers for addiction
5 services. Thank you.

6 DR. EGGERS: Thank you very much, Carol.

7 (Applause)

8 DR. EGGERS: And we have Jan.

9 JAN: My name is Jan. I am a woman in long-
10 term recovery, which means for me that I haven't used
11 drugs or alcohol for the past 31 years. Sustaining my
12 recovery allows me to be the founder and executive
13 director of SpiritWorks, which is a recovery community
14 organization in Williamsburg, Virginia, an ordained
15 deacon in the Episcopal Church, earning an advanced
16 masters of science in addiction studies, a board member
17 of Faces & Voices of Recovery, and a consultant and
18 subject matter expert on issues of addiction and
19 recovery.

20 I've been invited to share my perspectives,
21 specifically my experience with naltrexone. Back in
22 the day, for me, it was called ReVia. I took it for

1 about 7 years, subsequent to sustaining a traumatic
2 brain injury. What was happening was I was
3 participating in rehab to recover for my brain injury
4 and I wanted to maintain abstinence. The treatment
5 worked well for me as I was able to maintain abstinence
6 during a very stressful period of time in my life.
7 Success for me looked like I did not return to active
8 addiction, and I also experienced no cravings.

9 The biggest problems that I experienced were
10 associated with stigma as has been mentioned. It
11 happened for me when I went to pick up my medications
12 at the pharmacy until I developed a relationship with
13 my pharmacy and my pharmacist, ensuring that the
14 medication was available was a huge problem. ReVia was
15 something that was not kept in stock, which meant that
16 some months it needed to be ordered and required me to
17 wait for a few days, which meant that there were
18 periods of time when I didn't have it.

19 Also, there was a period of time when the cost
20 of the medication was prohibitive. I think that's
21 better now. I used to pay \$1,000 a month for it many,
22 many, many years ago. I do not currently use

1 prescription medical treatments to address my opioid
2 use disorder. Instead, I attend mutual support
3 meetings. I use my faith tradition friends and family
4 support. Doing so continues to work very well. I also
5 maintain a healthy lifestyle which includes proper
6 nutrition, sleep, and other aspects of health and
7 wellness. Maintaining what I call a culture of
8 recovery is critical to my recovery as it means that my
9 recovery is the most important aspect of my life.
10 Without it, as somebody has said earlier, I cannot
11 sustain life.

12 The treatments, therapies, and supports that I
13 have found most effective, I consider in two different
14 ways. One was the -- in the short term, I needed
15 medication, I needed counseling, mutual support
16 meetings, my faith tradition, family and friends'
17 support. Long term, I continue again with mutual
18 support meetings, faith traditions, and family and
19 friends' support.

20 The three major factors that I take into
21 account when making decisions about seeking out or
22 using treatments for OUD -- so the first one is that it

1 depends upon the specific treatment outcome that I am
2 looking for. In other words, that I need to know what
3 the reason is that I am taking a medication or seeking
4 a different type of treatment. I also need to know, as
5 Carol said, who are the people that will support my
6 decision. And I need to include them as accountability
7 partners. And also, accountability partners but to
8 also help me with my decision-making process in the
9 first place so that I know what my motives are and I am
10 doing things for the right reason. The other one that
11 I need, I think Carol also mentioned, I need a specific
12 plan as I engage in a particular treatment in order to
13 protect my recovery.

14 An ideal treatment for OUD, I believe,
15 includes medication for the biological piece. If it is
16 medically necessary, I think that therapy, some type of
17 counseling and recovery support services are critical.
18 Each of these components is necessary in order to
19 facilitate the achievement and maintenance of long-term
20 recovery. Their dose, frequency, and strength will
21 depend based upon the specific needs of the individual.
22 No one size of treatment fits all.

1 I think for me, and I was talking about it
2 with somebody at the table earlier that there were time
3 periods when -- I mean, recovery is not static. And so
4 what I needed in the beginning didn't necessarily look
5 like what I needed further down the road. I took ReVia
6 for about 7 years and I no longer take it. I needed it
7 during that time period. It's not something that I
8 required any more. I am grateful for the use of
9 naloxone -- excuse me, naltrexone during the period of
10 years, when I was experiencing a challenging time in my
11 life. Giving my success in using it, I would do it
12 again if the need presented itself. As I am very
13 motivated to maintain an abstinence-based recovery
14 program, taking naltrexone in pill form was effective
15 for me.

16 I do know of others who take VIVITROL
17 injections and that that has been a better method for
18 them, because it doesn't allow them to change their
19 mind for at least 30 days. And I also have been told
20 of people and worked with people who in their
21 desperation have removed their implants in order to use
22 -- so knowing -- as Carol said, knowing the best

1 patient for whom treatment is indicated is definitely
2 something that needs to be considered.

3 DR. EGGERS: Thank you so much, Jan.

4 JAN: Thank you.

5 (Applause)

6 DR. EGGERS: And finally, we have Daniel.

7 DANIEL: Hello. I am Daniel from Brooklyn,
8 New York. Thank you very much for having me. So I
9 just want to set the scene for a second here. So
10 picture this, that you're in a jail cell, by yourself.
11 You're about \$1 million in debt. You have no idea
12 where you are. Your girlfriend, at the time, comes to
13 pick you up, and it's about 3:00 a.m. in the morning
14 and you're in the middle of nowhere. And you get --
15 you know stumble your way into the car and you forget
16 who she is, like you didn't realize that that's your
17 girlfriend. So that was me about 5 years ago. Today,
18 I am 100 percent, I guess, clean or in recovery yeah,
19 for about 3 years. And that girlfriend at the time,
20 she is my wife now. So that's -- so I did that using
21 Suboxone treatment. So I guess I am the proof that
22 that treatment works. I am currently not on any

1 substance at all, haven't been for about 3 years, like
2 I said.

3 So essentially what happened with me is after
4 that scene that I just mentioned to you. I was put
5 into pretrial intervention program. I had good lawyers
6 who put me into that program. And basically I elected
7 to do the Suboxone treatment because that was one of
8 conditions for being a part of that. And you had to
9 kind of get your life together, get a job, et cetera.
10 So I did that. And why the Suboxone treatment works,
11 in my opinion, and I only share my opinion and what
12 worked for me because there are a lot of different ways
13 of getting there. But I can only share what worked for
14 me. And hopefully that helps the experts here figure
15 out what to do.

16 So the Suboxone works in my opinion because it
17 curbs the withdrawal, which is probably the roots of
18 the crisis because as you know those in -- who have OUD
19 will probably do anything to not experience the effects
20 of withdrawal or the sickness that comes with that. So
21 that's what leads to the criminal activity, et cetera,
22 in order to obtain more substances. So that's one

1 factor that's very important.

2 Another factor with regards to successful
3 treatment outcome would probably be the right social
4 environment, social setting. In my experience, it was
5 finding a -- it was being lucky enough to get a very
6 good job where I had a very strong support system with
7 the right people around me who supported me. I am not
8 sure if they even knew about my past. I guess it
9 doesn't matter. I felt very comfortable there. And I
10 think that that's essential. So that's the second
11 aspect.

12 And the third is creating a situation of
13 stability. So the job is one aspect of the stability
14 factor. With me, I think faith works for me. I am not
15 going to go tell you to become a priest, but it works
16 for me, or a rabbi but it works for me. So I found a
17 bigger connection to God. And like I said, I am not
18 pushing that because I know everybody has their own
19 relationship with regards to relations. So that's kind
20 of where I am at with that.

21 So I ended up tapering myself off the
22 Suboxone. I am not advocating that because I think

1 that if you are taking the pills or, by the way, I was
2 up to about 50 pills a day on my worst. So I was bad.
3 I was really bad. This was 5 years ago. So if you're
4 taking the pills, and then you got to stem the Suboxone
5 or whatever treatment to keep yourself off that, I
6 would say you should stay on that for the rest of your
7 life. But I elected to get off the Suboxone and I
8 tapered myself off eventually. So that's what --
9 that's my situation. And we got to help each other,
10 obviously. We all got to -- we're all on this
11 together. We got to help each other. I started a
12 website. It's called Dan's Recovery Team,
13 dansrecoveryteam.com. Check it out when you get a
14 chance. And hopefully -- we will beat this, we'll beat
15 this. All right. Thank you.

16 (Applause)

17 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 2

18 DR. EGGERS: Thank you to all the -- can
19 everyone hear me? Thank you to all of the panelists.
20 We hope that we found panelists who -- people who had
21 experiences with a number of different treatments that
22 we wanted to discuss today. And I thought that you've

1 all very well-articulated your journey, your
2 experiences recognizing that they are your own
3 experiences. And so what we are going to do now is to
4 see how we can expand upon those experiences. We'll
5 also get into some of the downsides of treatment in a -
6 - in another -- in a little bit. But first, first of
7 all, let me just ask one -- I usually do a show of
8 hands about how did you hear your own stories here.
9 But let me just talk about your journeys to recovery
10 and how they started. I thought you all articulated
11 that very well.

12 And did you see, it was a similar journeys to
13 recovery for you to -- okay. I appreciate how much you
14 had conveyed to us and reminded us of the complexity
15 and the difficulty of that. But now we are going to
16 focus in on medications and I have a polling question.
17 There aren't as nearly as many now, but I would like
18 you to answer a polling question so we get a sense of
19 the experiences with treatments in the room and on the
20 web. So if you can get the clickers handy.

21 This is -- check all that apply. So have you
22 ever used any of the following -- you or your loved

1 one? Okay. So the opioid agonist, that would be
2 methadone; the opioid antagonist, such as naltrexone,
3 which we heard about; the opioid partial agonist, such
4 as buprenorphine or buprenorphine naloxone; and that is
5 -- is that Suboxone -- and that's Suboxone; other
6 prescription or over the counter medications that you
7 have used to address your opioid use disorder. Other
8 medications that aren't mentioned, again, to address
9 your opioid use disorder? Or F, I've never used any
10 medications to address opioid use disorder. Okay. And
11 so we encourage you on the web to participate as well.

12 Okay, anyone still working -- okay, let's see
13 what -- okay. So we have -- basically we have all the
14 medications represented in the room. Methadone and
15 buprenorphine or Suboxone are the most represented.
16 Other prescription over the counter meds. And some of
17 you in here have never used any medications. Can we
18 see what the responses on the webcast were?

19 GRAHAM: Very similar. Almost the same
20 actually.

21 DR. EGGERS: Okay, I think there's one group
22 that has several people, who may have not used

1 medications. Let's start there actually and take a few
2 comments on, for those of you who are comfortable
3 sharing why you have not used any medications and on
4 the web as well. So we will come here -- you take,
5 Amanda.

6 AMANDA: Question what is Narcan, does it fall
7 anywhere on that list? So I mean --

8 DR. EGGERS: Narcan is just Naloxone. It's
9 not on the list of --

10 ANONYMOUS: No, because it's not a treatment.
11 It is an antidote to an opioid overdose.

12 DR. EGGERS: So go ahead.

13 AMANDA: Naloxone is part of the Suboxone
14 medication, so when you look at your Suboxone and you
15 see that there is a milligramage and then a slash and
16 then another milligramage, that's the naloxone portion
17 of the Suboxone medication.

18 ANONYMOUS: I chose to not use medicines to
19 recovery partially because of the amount of time that I
20 was in the inpatient detox. The other part was, I was
21 using opioids and Clonopin at the same time and
22 normally within the same quantities and because they

1 were so paired, they chose to taper me off and that did
2 kind of help-ish with my withdrawal. It handled the
3 mental portion of withdrawal and by the time I got into
4 other therapies like DVT and the length of time that I
5 stayed in intensive treatment, I was in treatment for
6 180 days. That kind of support and community
7 engagement of just recovery made it so that I didn't
8 feel that the medication was necessary. If I were to
9 relapse tomorrow, I probably would choose to do
10 medicine-assisted recovery, because a, I know that my
11 likelihood of maintaining recovery is higher if I use
12 medicine-assisted recovery and b, it is a safety net,
13 I have a child, I have responsibilities, I have a job,
14 and I want the dependency or the reliability that that
15 medication would provide me and I also know that second
16 relapse has much higher -- that relapse has a much
17 higher chance of me dying, and that and right now is,
18 you know, the shot I would have today is not the shot I
19 would have had seven years ago.

20 ANONYMOUS: Thanks very much.

21 DR. EGGERS: Any -- okay one so one more back
22 there and then we will get a summary, if there is any

1 web comments on this.

2 ANONYMOUS: I just want to first make the
3 comment that I'm a little troubled that this panel is
4 only made up of people who have used medication-
5 assisted treatments approved by the FDA and sold by
6 drug companies. There are a lot of other treatments
7 that work, that are not medication-assisted therapies
8 that the pharmaceutical industry profits off. I
9 spent seven years trying Suboxone, methadone, 12 Step
10 programs, various rehabs and what finally worked for me
11 was a substance called ibogaine that is Schedule 1
12 illegal substance in this country, thank you, and it is
13 not currently under investigation by the FDA. And I
14 want to ask why are we not talking about things like
15 ibogaine, why are we only focusing on long-term opioid
16 maintenance, not to just qualify anyone's valuable
17 experiences because I know those do work for lot of
18 people, but there are other options and I am little
19 troubled that this panel is only people advocating for
20 medication-assisted treatments. What about these other
21 options, not just ibogaine, but other things that
22 aren't even medication at all, why aren't we talking

1 about that. But something like ibogaine, which is the
2 only substance that removes opioid withdrawal that is
3 not another opioid, that you do not have to keep
4 taking. I did ibogaine six and half years ago and I
5 have not touched a single substance since and I do not
6 use medication treatments. And I just want to bring
7 this up and I want to have an answer as to why the FDA
8 is not putting any other resources they have to invest
9 getting this treatment. Yes they are death associated
10 with it, but there are deaths associated with any
11 medications. You have to follow a safety protocol for
12 any medication, so I would like to hear someone address
13 my comment about what I began.

14 PAUL: You know, I would've tried ibogaine if
15 it was available. I have to agree with you and I
16 didn't know that at least they're keeping the plants
17 alive, so they haven't killed it off completely in this
18 country, but it needs to be -- I almost went to Mexico
19 and did it, but I think, you have -- make a great point
20 that ibogaine is something that we don't talk about
21 enough.

22 (Applause)

1 ANONYMOUS: So the point --

2 DR. WINCHELL: Sure I will try to answer your
3 question very generally. I think most people probably
4 know that FDA doesn't actually do the research. We
5 provide some oversight, regulatory oversight to people
6 doing research and if people want to develop drugs that
7 they could bring to market, we provide them with
8 guidance and advice on how to design their trials and
9 when it's all finished they submit that application to
10 us and we vet the results and information about how
11 they make the product and so forth and eventually it
12 can come to market. That's why we are having this
13 meeting because we really want to understand how a
14 medication could be evaluated for effectiveness that
15 might be completely different from anything that we
16 already have available.

17 If something completely new, something totally
18 out of left field that wasn't an agonist, it wasn't an
19 antagonist, it wasn't a partial agonist or maybe
20 another other version of one of those, how should we
21 evaluate that drug and assess whether it's doing what
22 patients need it to do, and that's what wanted to

1 understand what you wanted to do. So FDA is quite open
2 to all different types of treatments and we just need
3 to get a better handle on how to evaluate them.

4 DR. EGGERS: So we probably won't be -- have
5 time to get too much of the experience with that
6 particular medication, but with the amount of clapping
7 that went on, I think there might be other experiences,
8 so please if you're on the web, feel free to write in
9 and this might be something consider putting a docket
10 comment with your experiences in your perspectives on
11 that.

12 Okay, so are there are any -- somebody is on
13 the web particularly about using any of the medications
14 any.

15 GRAHAM: Just a lot of people echoing what
16 they have been hearing in the room, and mentioning they
17 are using similar treatments.

18 DR. EGGERS: Great that is a great sign if we
19 can see echoing from the people on the webcast because
20 we know that it's difficult to make it here to the FDA
21 and so the fact that we are hearing echoes demonstrates
22 that there are a lot of -- that what we are hearing

1 here is shared with others. Okay, let me -- go head --
2 wait till we get the microphone.

3 ANONYMOUS: I'm a long term recovering addict
4 and for me, I had to treat my addiction when I was once
5 I got on the methadone, like if I had diabetes because
6 I used my (inaudible) of my choice to put faith, you
7 know, to have faith, knowing I can do all things, but
8 when I would try to get off the methadone I relapse
9 sometimes and it wasn't good. I would find myself back
10 out there, back in jail and I didn't want that. So I
11 said -- somebody told me, a counselor said try to treat
12 it. It's a disease, number one, you have a disease and
13 no matter what you have to face it, deal with it and do
14 what's best for you, you can do what nobody else do.
15 You have to do what is the best for you and that's what
16 I have done and it's has been 22 years today.

17 (Applause)

18 DR. EGGERS: Okay, thank you, we'll go back
19 there.

20 LOUISE: So I just -- my name is Louise and
21 I'm here as an patient and patient advocate and I am
22 here with Urban Survivors Union and we are a user

1 union. And some of my -- one of my questions is why
2 are we only looking at abstinence, as the only angle.
3 It seems that that's you know if we can only be
4 completely well or completely sick and there's a lot of
5 room in the middle and sometimes it takes a long time
6 to get from one place to another and sometimes we don't
7 want to get to the other place. So I think we need to
8 show some -- you know it would be interesting to me and
9 it would be part of, you know, what would help a lot of
10 the people that I know and work with, if there was
11 some, you know, some discussion about that.

12 DR. EGGERS: Okay, can I turn this question
13 around? Okay, let me ask you -- because we are going
14 to -- we are skipping ahead a little bit, you had good
15 insight into what we wanted to learn today. No, keep
16 the microphone there, what if it is not abstinence or
17 addressing withdrawal, what would you like, what would
18 you like it to do, a medication?

19 LOUISE: I would like to be able to manage my
20 use --

21 DR. EGGERS: Okay.

22 LOUISE: -- so that I can have the best

1 possible life you know, so I can show I am able to have
2 the best possible life I can have.

3 DR. EGGERS: And what is manage use, you mean.

4 LOUISE: Excuse me.

5 DR. EGGERS: And what is manage use. Describe
6 that to us.

7 LOUISE: Manage would mean, I am able to -- to
8 go to work and function and do what I need to do. If I
9 hadn't found drugs then I feel I would have probably
10 killed myself. So the alternative to what some other
11 people have said, they were using drugs and the drug
12 use made them want to kill themselves.

13 DR. EGGERS: Okay, can I get a -- do you feel
14 comfortable with a show of hands about how many people
15 -- you said I don't want to repeat your name for --

16 LOUISE: Louise.

17 DR. EGGERS: Louise okay, show of hands or
18 claps if you share Louise's perspective knowing that
19 not everyone shares it, but some do, okay. Any
20 questions you want for follow-up, any questions on
21 follow-up on that.

22 DR. AHADPOUR: So Louise hi, so I have talked

1 to you before, I'm glad you're here, this is Mitra and
2 we are looking at all aspects. I mean I think that's
3 one of the reasons, we are having this meeting that we
4 know recovery has different meanings to different
5 people and there is -- as someone said there is no
6 wrong door and there is no wrong approach. Everyone
7 has their own approach and some people want that total
8 abstinent, which is great, but at the same time it's
9 great to have not total abstinent. It could be that
10 you decrease your illicit drug use. You are on
11 medication, you're fully functioning, you have the
12 right relationships, you are working. So I mean you
13 are looking at all aspects because there is no one size
14 that fits all.

15 DR. EGGERS: So what I will do then, I will
16 suggest and we have to go back to a question, but so as
17 not lose this topic, I don't think we can spend too
18 much more time on that, but this is another great thing
19 for the docket or if you are on the website and you
20 share this perspective about wanting to manage your
21 use, try to be as concrete as possible about what that
22 looks like. Is it that you use only at certain times

1 of the week, is it that you need to only use at certain
2 times of the day that you can -- when you don't -- when
3 you absolutely can't use it that you're able to not use
4 it for a period, so be as concrete like that and write
5 in your comments, that is something that would be
6 extremely useful for our docket and for the webcast.
7 Okay and with that I am going to move to -- let me ask
8 -- I think there's a question from Allen one of our --
9 one of -- a person, who has been instrumental in our
10 planning. He is an FDA expert by the way.

11 DR. TRACHTENBERG: Thanks everyone for coming
12 up. I am finding your comments incredibly helpful.
13 This is the question initially for Paul because he
14 mentioned this other drug at the break, but anyone else
15 as well. What role do you see to be played or being
16 played by clonidine also known as Catapres in opioid
17 use disorder.

18 PAUL: I have only known clonidine to be used
19 in detoxes and to used to get high when you're
20 methadone. Does anyone else ever used it to get high
21 when there are on methadone, anyone in the room. I am
22 the only person.

1 DR. EGGERS: Okay, you got another hand right
2 beside you.

3 PAUL: How about because it intensifies -- and
4 I never knew you could do that until I tried it because
5 they are selling it outside the parking lot, but
6 clonidine and (inaudible) intensifies itself, but by
7 itself I had used it for detox and it was quite
8 effective.

9 DR. EGGERS: So we will take one more. Is
10 this comment about this? Is your -- no, okay.

11 ANONYMOUS: I mean with all these alternates,
12 you know what for me the methadone was the alternate
13 for the heroin and which worked good for me, you know,
14 through the years, but my question is somewhat in view
15 of this is, what is the ultimate answer for someone to
16 get to the abstinent point, was it another drug and as
17 in that falls behind the methadone process. Or if you
18 want to -- in order to get to the abstinent goal, to
19 come off methadone all together.

20 DR. EGGERS: So the question I think, is your
21 question what, the question is your raising is if you
22 don't want to be a methadone, what's your -- what do

1 you do next, what's your next.

2 ANONYMOUS: What's the next move, yeah.

3 DR. EGGERS: Okay. So I don't know if we have
4 the answers, but sure some I -- maybe a few ideas.

5 ANONYMOUS: You don't have to get on methadone
6 if you're heroin, you can get on heroin maintenance and
7 if it is prescribed and regulated dose like they do in
8 Switzerland, the U.K. and several other countries in
9 Europe, you don't ever have to transfer your dependency
10 to methadone, you can stay on heroin become stabilized
11 more quickly and even better if they offered a
12 supervised injection facility for folks to come in be
13 monitored so they don't overdose and die. That's the
14 way that works since its proven to be effective in
15 Canada and other countries, so we need that in United
16 States.

17 DR. EGGERS: Let me ask in a different -- let
18 me ask this a slightly different way, what would you
19 like if you are on methadone and want to get -- not to
20 be using -- what would you need to see for your health
21 benefits if you were to go onto a different treatment,
22 what you need to see. Let's go here, we one here and

1 then one in the back there and then we are going to
2 take a break, a 15-minute break.

3 ANONYMOUS: Well I on methadone and I think
4 the outcome is that once you stabilize your life like I
5 have and you can go back to start doing things to
6 implement yourself in society again, then take a long
7 term detox off. You don't rush off methadone, but you
8 can take a long term detox, that eases your way down,
9 eases your way down to where become un-dependent on it.

10 DR. EGGERS: So that would be your goal. So
11 that's your goal too. We have one, okay anyway we got
12 a couple different same goals, one more over there and
13 then we will take a break.

14 ANONYMOUS: Okay you stay on treatment, stay
15 on treatment and you keep going to groups and you
16 listen that's how you get off.

17 DR. EGGERS: Okay, all right, so it sounds
18 like this you guys will have -- there will be some
19 break conversations at your table. I think this has
20 stirred up a lot of great insight and sounds like of
21 interest to you. We are going to take a break and then
22 we are going to have keep moving on. We have a few

1 other questions that we want to get to, so we will be
2 for 15 minutes. Please come back at 2:35.

3 BREAK

4 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 2

5 CONTINUED

6 DR. EGGERS: There is the bus that's going to
7 Union Station so taking the downtown DC, has plenty of
8 space on it. Its leaving at 4:00 o'clock and our
9 meeting will end by 4:00. So if you in the downtown DC
10 area, then please feel free to take the shuttle and I
11 don't even know the name of the woman in the red
12 blazer, but she is the one who told me. So you have
13 more information right, if people need it.

14 Okay let me just go get my microphone and get
15 myself situated. I think we were wishing we would have
16 planned like a two-day retreat for as much as there is
17 to talk about and share regarding your experiences with
18 opioid use disorder.

19 Unfortunately, we have you know about 40
20 minutes left and what we really want to focus in on is
21 how can we make medical treatments better and have them
22 have the end -- have them achieve. You heard it early

1 this morning a lecture I talked about end points and
2 what that means is a drug has to show that it can have
3 benefit for you and it has to show in a very concrete
4 specific way. You have to be able to say, "I know this
5 drug shows benefit in people," and so what our job is
6 to translate the things that you're really caring about
7 into those concrete things that can be measured at the
8 end of the day, such as we were talking the woman in
9 the shirt -- about reducing use, and so we want to get
10 in to more of those aspects. What does this look like?

11 Okay, so I first want to, I am just doing a
12 little bit of real time math here. It's so hard when
13 you have 200 people looking at you doing math, yes.
14 Let's skip the next polling question and go on to the
15 third -- the polling question we are going to skip was
16 about the downsides of treatment and I think you have
17 been very clear in the downsides. Do you have
18 something you would like to -- okay we will let you go
19 and then I will go with the polling question.

20 STEVEN: Hello my name is Steven, once again I
21 am here with Mend a Life program and what works for me
22 was, I have been on the program for nine years and what

1 works for me was the methadone as well, but today is I
2 can say that this my first year of actually being
3 clean.

4 DR. EGGERS: Okay, okay.

5 STEVEN: Now, what I was saying --

6 DR. EGGERS: And by that you just mean that
7 you are not using.

8 STEVEN: Nothing at all, right, but what I
9 saying that the time it took so long for me to get to
10 this year was that I had needed mental health to help
11 me realize and to come out of denial about being on
12 drugs and other things such as abuse coming up and
13 everything that goes into mental health. I believe
14 that if there was more mental health accessibility in
15 programs, it would help out a lot.

16 DR. EGGERS: Okay so I want to clap, so a show
17 of hands if you agree with what you just heard.

18 (Applause)

19 DR. EGGERS: Okay and I think -- yes okay, all
20 of the FDA people are clapping too. I think that has
21 been made crystal clear and I think that it's well
22 understood the need for the -- who said it up here and

1 so nice that the three things that are needed together
2 the supports, the counseling, the medical treatments if
3 that's necessary. And what we want to do moving
4 forward is -- let me do a show of hands, how many of
5 you believe that medical treatments is a necessary part
6 of your OUD, even if you don't use them now, it might
7 be a necessary part of your OUD to manage your
8 condition. I think medical treatment in terms of the
9 type of medicine that you would get from your doctor.

10 DR. HERTZ: Yes so the traditional medication
11 assisted therapies.

12 DR. EGGERS: Yeah. Okay so raise your hand if
13 you believe that medication assisted therapies as
14 Sharon just described are a part of -- you can see as
15 being part of your management needs. Okay then show of
16 hands of those who do not. Okay, so we do have some.
17 What we are going to go through now and we're going to
18 assume that someday there will be newly -- the FDA will
19 be able to approve new medications to help you manage
20 your OUD in all the ways we been talking about today.
21 Okay, so can we go -- we will go on, okay one more,
22 keep going. Next polling question. Okay so here's

1 what we want to think about, is what would any -- if
2 you are --even if its currently approved drug and you
3 could consider taking it of any treatment, when
4 considering a new treatment even one that's not yet --
5 even one that's not yet here for opioid use disorder,
6 which of the following benefits would you consider to
7 be most meaningful in your current life situation. So
8 a, help me control my use of opioids better so that I
9 can function that was what we heard back at the table
10 over there, okay. B, help me achieve complete
11 abstinence of opioids. C, reduce effects of opioids
12 withdrawal. D, reduce the effects of opioids cravings.
13 E, reduce how often I have to take the treatment. B,
14 allow me the ability to take my medication at home or
15 G, some other benefit that's not up here, we are going
16 to explore these benefits.

17 So you can choose up to two things. Is
18 anything unclear about the question? What's most
19 important to you about a treatment, what will it do for
20 you, is there a question, do you have a question.
21 Okay, we will wait till we see the results. And on the
22 web on please chime in this is -- it's got a big

1 highlight on my sheet here. This is probably the most
2 important question that that many of my colleagues
3 would want to hear. Okay, do some people need clickers
4 and they don't have them. We will bring clickers to
5 you. Okay let's go to the results okay. Okay you've
6 made our discussion difficult because you picked
7 everything. So let's start with the most, the one that
8 got the most in the room and on the web what results
9 are we getting?

10 GRAHAM: Actually quite different from the
11 web. We have about 73% saying reduced opioid cravings
12 and then about 40% controlled use of opioids, 30% for
13 complete abstinence and reducing withdrawal and in less
14 than 20% for the rest.

15 DR. EGGERS: Okay, now from here on out, let's
16 try not to speak about specific medications because
17 they are moving for -- we don't care about what
18 medication it is, we just care about what you really
19 are looking for out of a treatment, and I noted at the
20 beginning that there are differing perspectives in here
21 and so we want to take both of these together because
22 hopefully someday, there will be medications that meet

1 whatever your needs are.

2 Let's take here B because it was most --
3 slightly more in the room. How many achieved complete
4 abstinence of opioids. First let me -- is there is any
5 clarification, any question from my FDA colleagues
6 about a type of endpoint that you would like to ask
7 about here. While they're thinking -- what just --
8 what is it if it is different than what you have
9 already because I have to ask and recognize a lot of
10 you here in the room are currently abstinent from
11 opioids. So you might have to go back into your
12 memories about when it was more difficult or think
13 about potential for relapse.

14 Okay, what would you want to get out of that,
15 what would -- what would it -- how would you describe
16 what you're looking for there. We will start with
17 Amanda and then we will go here.

18 AMANDA: Think of it similar to when you're
19 talking to a patient with chronic depression and you're
20 hitting some of the points. So you may have an
21 medication that handles the cravings okay, but it has
22 some serious side effects that are similar to when you

1 were in active use and understanding that we found a
2 couple of medications that work really well, but there
3 needs to be a combination of things and there also
4 needs to be an understanding that if you have opioid
5 use dependency or you have opioid depression and you
6 are treating that with a medication that's derived from
7 opioids, the depression is still there.

8 So it would be nice if there was a way to have
9 a medication that would make our brains not crave the
10 drug and also have something similar to that SSRI to
11 help handle some of the anxiety, help handle some of
12 the depression. I think a good chunk of us in this
13 room have experienced the benefits of Trazodone because
14 it does help us go to sleep with a nonnarcotic
15 component and have that be something that kind of
16 prolongs, you so you can hit two birds with one stone.

17 DR. EGGERS: And you're saying decrease the
18 stigma.

19 AMANDA: Yeah.

20 DR. EGGERS: Okay so back here we had okay
21 yes.

22 SHARON: Excuse me, it's Sharon again. My

1 question is does -- is there any research into
2 medications that are not opioid based for withdrawal,
3 because to me it's like somewhat like exchanging one
4 opioid addiction for another.

5 DR. EGGERS: Okay I'll let -- see if Sharon
6 wants to answer the question.

7 DR. HERTZ: I have a couple of comments on
8 that. We just heard two comments about replacing one
9 opioid with another and I'd like us to follow up on
10 seeing how much people really believe that being on
11 medication assisted therapy with something like
12 methadone or buprenorphine is simply replacing one drug
13 with another versus is it an active treatment for a
14 condition, but in terms of what's available to manage
15 withdrawal we recently had an advisory committee
16 meeting. So I can tell you about this because it's
17 public. For a drug that was being developed to help
18 reduce the symptoms associated with a fairly rapid
19 detox. Now the pros and cons of rapid detox and what
20 was going to happen next were not the question, but so
21 there is a drug that is under review to help reduce
22 those symptoms.

1 One of the questions that came up during the
2 committee was about longer-term slower detox and that's
3 an outstanding question. So there is some research in
4 there, but that's what I can speak about in terms of
5 what's been public.

6 DR. EGGERS: Okay. So let me just do a show
7 of hands to Sharon's question about -- let me frame it
8 as a goal. How many of you would, as a goal, for those
9 of you that are currently on one of those products
10 we've been talking about or your goal is to not be on
11 it. How many of you -- show your hands, would be
12 willing to take a medication for up to the remainder of
13 your life to address your OUD? Show of hands.

14 Yet if you have to take a medic, you -- so
15 maybe it's not the medications that we're talking about
16 the ones that you think are might be replacing one for
17 the other, but it was some other medication. Are you
18 willing to take a medic? So it's not the fact that
19 you're not willing to take a medication for the rest of
20 your life. Are you -- show of hands if you'd be
21 willing to take the medication? Okay that -- we're
22 getting a lot of head nods that, yes, you'd be willing

1 to take a medication. Now how many of you would rather
2 -- your goal is to be able to get off one of the
3 treatments that we've been talking about?

4 Okay, you're willing to take some other
5 medication for the rest of your life, but maybe you'd
6 prefer to not be on this one. Okay. So we're not going
7 to discuss that. But we do note that that is then a
8 perspective that's out there. You can make one comment
9 -- yes, sure. Let's let like a brief one.

10 DANIEL: Yes, super brief. Just with regards
11 to that, how the -- if being on something like
12 Buprenorphine is replacing one substance for another or
13 one drug for another, I guess, technically it is.

14 But I feel like Suboxone, for whatever reason,
15 because of its chemically designed to do so, it allows
16 you to reenter society and become a functioning part of
17 society again. And I think that that's essential with
18 regards to maintaining a basically -- in recovery
19 that's essential.

20 So if that requires you to stay on it for the
21 rest of your life, in my opinion, I think that that's
22 better than any alternative. And obviously, I think

1 it's probably a extra to get off this -- the
2 Buprenorphine, that's an extra step. Right? So if you
3 want to attain that, I guess, "higher level", I don't
4 know what you want to call it, but I don't think it's -
5 - I think it's best to stay on that.

6 DR. EGGERS: Okay. So then you're -- so
7 you're adding -- so again, this is a very complicated
8 issue, because you're adding then to say that if you
9 need it you need it, right. And so that's what it
10 sounds like we're hearing from a lot of you in the
11 room.

12 Okay. We're going to take a maybe, what might
13 be a couple other perspectives, just a few of you, and
14 then we're going to move on and talk. Okay, go ahead.
15 Let's see, the woman back, yes.

16 ANONYMOUS: I just -- I'm struck by the way
17 that we talk about this kind of treatment for substance
18 use related problems that's so different than every
19 other kind of treatment that we talk about.

20 So if you had problems with anxiety and you
21 went to see a therapist they would say, you know, we
22 have different options. We can give -- we have

1 medication that we can give you. We can do behavioral
2 intervention and you -- teach you breathing techniques.
3 We can do talk therapy and delve into your childhood
4 trauma and see where this came from. And some
5 combination of that will probably be helpful to you.

6 But if they said, if you follow our treatment
7 plan you will never ever be anxious again in your life.
8 You would say, "You're crazy. That's ridiculous." But
9 that's what we do with drug treatment as we say, if you
10 follow this plan, the goal is that this problem is
11 going to be completely gone when -- you know the
12 reality is that it's like most other things in life
13 that they are -- sometimes you deal with it better and
14 there are periods where it doesn't go as well. But we
15 see it as this completely discrete other thing. And I
16 think that's one of the big problems --

17 DR. EGGERS: Okay. Are you speaking of
18 abstinence right now that if you follow our plan you
19 won't use again or --

20 ANONYMOUS: So, I mean, you might have
21 somebody.

22 DR. EGGERS: Yes.

1 ANONYMOUS: You might have somebody who, in
2 fact, is able to never ever have another episode of
3 anxiety in their life, but that's highly unlikely.
4 That for most people it's a treatment plan for dealing
5 with anxiety disorder.

6 Usually, looks like client will reduce number
7 of panic attacks per week, will learn strategies for
8 coping with feelings of anxiety and a typical treatment
9 plan for substance use disorder, having seen many of
10 them in my life, is something like client will refrain
11 from any illegal drug use. Client will not relapse to
12 illegal drug use.

13 DR. EGGERS: So give me another one. Give me
14 -- what do you wanted to -- give me something you'll
15 say client -- individual will what -- give me another -
16 - give us an alternative and then I think we can work
17 with that.

18 ANONYMOUS: Yes. Well -- I mean, I think,
19 people have said this. What you -- I mean, I work for
20 a syringe exchange program and when I look at the data
21 that we've had in terms of what drugs people use and
22 people who say that they use Suboxone, over half of the

1 people who report that they use Suboxone, say they use
2 it sometimes, not daily.

3 So, obviously, it's something that's helpful
4 to people, but not necessarily exclusive to -- to the
5 exclusion of other drugs. And I mean I know there's
6 been research that shows that people who use illegal
7 drugs, but also use Suboxone do better than people who
8 don't use Suboxone and use illegal drugs.

9 So, I think, as for everybody, people want to
10 have some control over the unpleasant symptoms in their
11 life, which are various and they're different for
12 different people. And so I think looking at that piece
13 of it -- that if -- I think about what I've read about
14 naltrexone use -- occasional naltrexone use for
15 alcohol. That people who say when I want to drink I
16 take naltrexone and I don't drink as much and that
17 works for me.

18 That if there are ways that -- I mean, that
19 the end point, the goal in all of the discussion has
20 been zero you -- not using any of a certain kind of
21 drug. And if you back that up and look it like we use
22 -- you know most other behaviors that goal is how to do

1 -- how to be able to manage things yourself so that you
2 function in the way you want to better.

3 DR. EGGERS: Okay. So let's then transition
4 to A, to help me control my use of opioids -- help me
5 control my use of opioids so that I can better
6 function, I think that's one area you're going into.

7 What is it -- I'm going to throw out an
8 example that's probably wrong, okay, so you can correct
9 me and then give me a better one. But to say that I
10 have my family visiting for the next two weeks and I
11 would be able to not use or cut down or something like
12 that while they're here. And I fully plan on using,
13 again, to some higher level, after my family is gone,
14 because it's probably the wrong example, you can tell
15 me that and then tell me something better. Anyone,
16 anyone? So we'll go there. Amanda, first and the while
17 you are thinking we'll go to --

18 AMANDA: I totally did that. You have
19 functions -- you need to appear normal, so you think
20 about setting yourself up. That was normally when I
21 would pay more money for prescription medication,
22 because I would need it in such a high quantity to

1 equal the kind my tolerance that I had gotten at that
2 point on heroin.

3 That would be kind of the land also where I
4 would think about going out and grabbing Suboxone as
5 well, because that -- I could do that for a short
6 period of time and then taper myself back on to
7 whatever I was using. That was what it was --

8 DR. EGGERS: And then back there -- couple.

9 ANONYMOUS: So I was just thinking like I'm
10 going to work all week long. And then when it comes to
11 the weekend, because I'm an adult, I'm going to do what
12 most Americans do, which is have a drink or if that's
13 not so what should I do, I'm going to use opiates. So
14 that would be sort of the way I see this.

15 DR. EGGERS: So control it for some period of
16 the -- now what -- can I ask -- what would it take to
17 do that? So how -- what would it take for you to be
18 able to control it during the week and allow you to
19 then use more and then be able to control it again?

20 Can you think of would it have to reduce your
21 cravings during the week or would it have to affect
22 your withdrawal during the week?

1 ANONYMOUS: Right. So it would have to affect
2 a lot of things. But it would certainly have to affect
3 withdrawal. It would affect anxiety, depression, maybe
4 obsessive thinking.

5 DR. EGGERS: Okay.

6 ANONYMOUS: That's sort of the best -- sort of
7 a negative self-talk kind of dialog, so it would have
8 to affect all of that.

9 DR. EGGERS: So let me ask another one. I'm
10 going to throw out again probably the wrong example,
11 but you can correct me. Imagine you have gotten
12 yourself to a point where you don't like how much
13 you're using, but you don't want to -- you want to go
14 down all across the board. You want to go down a bit.

15 Talk about that, is that a realistic type of
16 point that you'd like you'd be able to cut it in half,
17 because it's getting -- you're doing dangerous amounts
18 or you're worried about overdose or other risky
19 behaviors. Okay, go ahead. We'll let you answer or --

20 ANONYMOUS: I think people do that all the
21 time with either through kratom, marijuana, meth use
22 like cocaine. People use in a way that makes it so you

1 maintain your own self.

2 And the reality is people don't go to
3 methadone or Suboxone, because we decide to put so many
4 barriers in their way to make it so hard to engage
5 those systems that -- like, legal -- like, I live in
6 Washington and so legalized marijuana has been more of
7 a treatment seems to be for opiate users even though
8 it's not scientific or anything like that.

9 And like -- for example, kratom, people will
10 use kratom during the week and they'll shoot heroin in
11 the weekends. And so all of these things that people
12 are using because the medical field has been locked
13 out, because we've decided to make it too hard to get
14 these medications.

15 DR. EGGERS: So let me -- keep that -- keep
16 the microphone. Let me ask you, so again we don't want
17 to talk about specific treatments and I -- and not all
18 treatments can become FDA approved.

19 ANONYMOUS: Sorry.

20 DR. EGGERS: What is it -- how is it helping
21 people -- what would you want it to see to say, I'm at
22 a level that's too high for me. I'm going to -- I want

1 just to cut back. Tell me in concrete terms what that
2 would do for you? Does it take a little edge off?
3 Does it reduce your cravings, but -- so that you don't
4 crave as much? Okay.

5 ANONYMOUS: I can give an example through
6 methamphetamine. So we -- I run a needle exchange and
7 we gave out meth pipes, and a huge portion of meth
8 injectors switched to meth smoking. And the number one
9 thing they said is now they can make their
10 appointments. Now they can meet their doctors. They
11 can see their family. They can do all these things
12 while still using -- and all they did was change the
13 mode of how they ingest the drug and not change
14 anything around what drug they're using.

15 DR. EGGERS: So if I can make parallel -- so
16 maybe it's changing to safer forms or less potent forms
17 -- I may come to that. Okay. So those are the types
18 of outcomes. So I think we're going to move on from --
19 okay, go ahead. Yes, please.

20 ANONYMOUS: I just want to say back when I
21 first started using methadone it was like maybe come to
22 that point which is like, if you use all week -- right?

1 I was wishing that it was a methadone program, where
2 you could just go on a weekend like -- like you say you
3 want to get to a certain stage, maybe you go and it
4 will hold you for that weekend or something. Then you
5 wouldn't have to use it every day where it becomes
6 dependent on methadone. You see, that was to me a good
7 solution in the beginning. But like you said, you got
8 to -- in all the way or you're not in at all.

9 DR. EGGERS: Okay. Thank you for that. I
10 want to move on to craving because we talked about what
11 craving means and what struck me was how craving can
12 still affect, can still be a problem even if you've
13 been in recovery for a long time.

14 So tell me about that. What does it -- what
15 could a medication do that could help -- I'm -- okay,
16 I'm going to give again the wrong example. But imagine
17 that you are worried about relapsing, that's maybe a
18 big concern you have and something that could help you
19 get through periods of -- you know that there's going
20 to be some high anxiety or stress that or maybe you're
21 going to be in a situation where you're going back to a
22 type of situation that you might have used before in

1 that type of situation.

2 If something could help with this idea of
3 cravings, however you think of it. What would that do?
4 Would it take the edge off? Would it -- how could it
5 help you cope through those situations that can be very
6 challenging? Anyone? Does that question makes sense?
7 Okay, go over there and then we'll come over here.

8 KEVIN: Hi. It's Kevin again. So I relapsed
9 a year and a half ago after almost 6 years of sustained
10 abstinence and recovery. And I am 12 years -- 12 days
11 since arresting that relapse. So basically the
12 position that I found myself in was a highly traumatic
13 life event that happened at a period where I had no
14 support structure around me. I had abandoned
15 everything that had worked thus far.

16 So the one example that I was personally
17 affected by was death of a loved one. My father passed
18 away. And even though my family knew I was in
19 recovery, I didn't tell them that I was -- all of a
20 sudden in a highly vulnerable state.

21 DR. EGGERS: Yes. Okay.

22 KEVIN: So perhaps we as a society might

1 recognize that if I had -- and I had relationships with
2 a therapist, my primary care physician. They know my
3 condition. They knew about my father's passing, but
4 nobody really asked me, what's your craving level right
5 now? Do you want to go out and go get high? And most
6 people would assume that that might happen.

7 The other example I'll give is not my personal
8 example, but it's been echoed a lot of concern about
9 people going in for medical treatments, surgery. If I
10 have to go to surgery and I'm going to be in a lot of
11 pain, I'm asking for opiates. I don't care. Opiates
12 work very well at mitigating pain and if I'm under the
13 care of a doctor, I can trust those around me that I
14 can get through that without relapsing.

15 However, the current state of affairs today is
16 a very similar situation. I read a report in STAT News
17 by Seth Mnookin -- not Seth Mnuchin. Seth Mnookin, who
18 went to Mass General Hospital to receive surgery for
19 kidney stones, and even though his PCP knew he was 20
20 years in recovery from injection drug use, his wife
21 knew, no doctor at any point ever gave him a
22 consultation about the take home pills that they were

1 handing him and all of a sudden he found himself
2 physically dependent two weeks later not having had
3 experienced that in decades.

4 So we need to recognize these highly
5 vulnerable states that people with opioid use disorders
6 will encounter in their life and they need to be given
7 the proper outreach and support throughout those
8 decisions, whatever they make.

9 DR. EGGERS: So think about FDA's rule.
10 Sorry, I'm going so off script. I'm sorry. Can
11 medications help with that? So I am think -- so what
12 comes to mind is the idea of the rescue. But so you --
13 and we've all acknowledged the need for support, but
14 would you want a medication that could help you help
15 get through that traumatic lifetime that could reduce
16 your risk of going back, of relapsing abusing again?
17 Okay, so right here we have Jane.

18 ANONYMOUS: Sure. So, yes, that was my
19 experience. I was having a very difficult time after
20 having a traumatic brain injury and wanting to make
21 sure that I didn't start using opiates again. And so
22 that's why I took naltrexone.

1 The other thing is, after having a surgery I
2 do have a really wise doctor who knows my condition.
3 And so I went in and had detox and was inpatient in
4 residence, while I needed to do that, so that I didn't
5 just get put back out on the street. And I have a
6 really tight opioid use plan and so it includes all of
7 those things.

8 I mean recovery planning is -- for me a part
9 of my recovery supports and makes a difference and it
10 does allow me to be in control even when I'm not in
11 control. So it's like a -- what do you call it, a
12 medical advance directive. So I made my plan when I
13 was in a really good place. And so when I'm taking a
14 medication that doesn't allow me to make decisions for
15 myself. I have people who are allowed to step in and
16 make decisions for me at that time.

17 DR. EGGERS: Okay. So, yes, right.

18 ANONYMOUS: Yes. I think that having some
19 type of intervention -- I'm not sure that I agree with
20 the notion that all FDA can do is produce medication.

21 DR. EGGERS: No I just think of one role that
22 we do.

1 ANONYMOUS: Yes. I do think you have other
2 authorities that you could use to help in this area.
3 But that being said, I think some type of intervention
4 to help manage stressful situations, maybe they're drug
5 related and maybe it can be devices and apps and other
6 things. I think that I am very visual and when I see
7 products that I was formerly addicted to, it can set
8 off and trigger cravings.

9 And I think it's important that these cravings
10 are for more than things other than just opioids and
11 that drug development or device or app development that
12 can target that reward system in the brain. And I'll
13 give you an example about physical craving. With 10
14 years in recovery, when I put my ATM -- my credit card
15 in an ATM, because I used to use all night and I would
16 go to the ATMs and maybe there was money in there and
17 maybe there wasn't, for many, many, many, many, years.
18 I was a working person, so I was lucky. But you'd run
19 out, obviously.

20 And my stomach after -- even 10 years in
21 recovery, would still flip when I was at that ATM
22 machine. I would get that -- there's that 20 seconds

1 before you know whether cash is coming back out or not,
2 and your card is coming back out. And I would still
3 feel physical sickness about that longing and that
4 craving after 10 years.

5 So don't think that physical craving isn't a
6 problem. And I can get that where I can get the taste
7 of alcohol when I'm -- in my job there's a lot around,
8 and I can actually get the taste of it when I'm
9 stressed and seeing it everywhere. So things that
10 could address that that are really brain oriented, I
11 think, or gut oriented or heart, I don't know, but some
12 organ.

13 DR. EGGERS: And would you consider a medic --
14 so if this -- I don't -- not say that it rises to the
15 level of a challenge -- sorry, go ahead.

16 DR. WINCHELL: I do have a follow up on that,
17 because in particular, many people are interested in
18 this concept of craving. If there was some type of
19 medication that could prevent you from feeling that
20 experience, is that something you would find helpful
21 all by itself. It wouldn't necessarily change anything
22 about the way you use drugs or any other aspect, but

1 just that one symptom, would be beneficial.

2 ANONYMOUS: Absolutely, I will take it, yes.
3 For me -- and this is not the way it is for everyone,
4 if it's mood altering it tends to trigger me wanting
5 more mood altering medication. If it's simply cure
6 cravings, I'd be first in line, because I still over 20
7 years have problems with various kinds of cravings.

8 DR. EGGERS: Hand raises if you agree with
9 this perspective. Okay. So we will come right here --

10 DR. WINCHELL: Can I?

11 DR. EGGERS: Yes, of course.

12 DR. WINCHELL: So that's a very interesting
13 perspective from someone in long term recovery who
14 still struggles with those very unpleasant experiences
15 of craving. Suppose someone who is in an early phase
16 trying to get control of their drug use had a
17 medication that made them experience the cravings less
18 intensely, but didn't -- that didn't translate into any
19 modification of how much they use medications. Would
20 people in early recovery or people actively using and
21 looking to gain control would they find that helpful?
22 Just this is part of what --

1 DR. EGGERS: Might like to be for the dockets,
2 so I think we have lot of people in --

3 DR. WINCHELL: Yes.

4 DR. EGGERS: -- sort of long-term recovery.
5 But if you are on the web, please do and if -- and on
6 the docket, unless someone wants to talk about that.
7 You -- did you want to address this question? Okay,
8 you want to address this question?

9 RICHARD: In a general sense, yes.

10 DR. EGGERS: Okay. We will let you go first
11 and then we'll go back.

12 RICHARD: Yes. My name is Richard REDACTED.
13 I'm a professional documentary filmmaker from
14 Baltimore. And my wife Margaret REDACTED is an
15 associate professor in psychiatry at Johns Hopkins
16 University School of Medicine. She's an addiction
17 certified researcher and educator. Today, she's taking
18 care of patients and I will be representing excerpts
19 from her written comments on behalf of our family.

20 We are the parents of a 25 year old son with
21 opioid use disorder. My wife heard about this meeting
22 from her colleagues and decided to comment because she

1 cares as a mother and an addiction professional. I'm
2 here at my own time and expense, because I see what
3 kratom has meant to our son and our family and hope
4 that he and others will have access to this drug, which
5 we came across in the last year because of his use of
6 it. So her statement and I'm going to read her
7 statement.

8 DR. EGGERS: We only have a few more minutes
9 left. Is this something we do it at public comment?

10 RICHARD: I just arrived here. I'm sorry if
11 I'm not in the right place at the right time.

12 DR. EGGERS: No, no, that's fine. If you
13 could just keep it brief.

14 RICHARD: I'll consolidate it. So he's been
15 struggling with opioid use disorder for the last 4 or 5
16 years, in and out of college, in and out of treatment.
17 He was on buprenorphine for 2.5 years and he was unable
18 to work and lethargic during that time. And so we've
19 been through the mill as many people and many families
20 have.

21 And after he was -- a few relapses and after
22 he was living in Seattle in a sober living facility, he

1 started using kratom, I guess he heard about it. He
2 was sober. He was going to meetings and he started
3 smoking kratom to stave off his cravings.

4 And because living facility tested for kratom
5 and kicked him out, he was almost homeless briefly and
6 then he decided to go back to college. He now smokes
7 kratom occasionally as a maintenance for the craving.
8 He has a girlfriend. He's back in college. He just
9 visited us and he's in better shape than he's ever
10 been.

11 And so as a family we're concerned about
12 kratom becoming inaccessible to people like him,
13 because it's been sort of a -- if not a lifesaver, it's
14 been a very, very efficacious way for him to have
15 survive.

16 DR. EGGERS: We want to hear all experiences
17 about -- we welcome experiences about all products and
18 especially through the docket or through the webcast.
19 And so thank you for sharing your experiences. We
20 won't be able to get into that discussion in any depth.

21 There was one more answer about the -- on the
22 question that Celia posed about reducing craving.

1 ANONYMOUS: So I think we need to think of
2 drug use a little differently. I think we need think
3 of the chaotic drug use and stable drug use and how can
4 we get as many chaotic drug users into stable drug
5 users, because, I think, the concept of recovery that
6 can be their form of recovery. And I also think that if
7 we could get more people on to stable use then we can
8 start engaging them in myriad of other health related
9 issues. And I think that's how we really need to see
10 this.

11 DR. EGGERS: Okay.

12 ANONYMOUS: And I think we have a lot of
13 people in recovery here and so it's been very kind of
14 recovery focused. But I think it's really important
15 that we, like, really get in depth of defining chaotic
16 use compared to stable drug use and how we can support
17 people on stable drug use and how we can get as many
18 chaotic drug users into stable drug use.

19 DR. EGGERS: Okay. We aren't going to able to
20 follow up that now, but you promised to send in a
21 docket comment, define chronic stable drug use and
22 chaotic and what it means. Go ahead, Sharon.

1 DR. HERTZ: So I would just like to ask this
2 is really interesting for us and I would like to
3 encourage people as much as possible to send in
4 comments to the docket so we can hear as much about
5 that as possible. But that's I think very important.

6 DR. EGGERS: Okay. We are --

7 DR. TARVER: I'd like to ask one more question
8 too.

9 DR. EGGERS: Yes.

10 DR. TARVER: You also mentioned that some of
11 you are reluctant to want to use medication. I'm just
12 curious as to whether anyone in the audience has used a
13 device or an app to help manage their condition?

14 DR. EGGERS: Okay. First let's split out, an
15 app -- some sort of app, okay. Another kind of device.
16 Okay. Let's just get a -- can we get a quick -- just
17 quick what it was?

18 ANONYMOUS: Yes. I used the Calm and
19 Headspace meditation app to chill out anxiety and help
20 manage stressful situations. And I've used a device
21 that monitors my sleep, because lack of sleep makes me
22 start craving and basically just be off.

1 DR. EGGERS: Anyone else device? Anybody
2 here?

3 ANONYMOUS: I've used the Spire device and so
4 it monitors your heart rate variability and can
5 identify when you're having anxiety attacks.

6 DR. EGGERS: Anyone? And then we'll go to
7 Amanda.

8 ANONYMOUS: I'd used device for -- since I was
9 an orthopedic client to be replaced with (inaudible)
10 purchased through my doctor what they call (inaudible)
11 and this is an alternate for pain control without
12 taking anything by mouth or any other way. And I used
13 it temporarily.

14 DR. EGGERS: Finally, Amanda.

15 AMANDA: The Alpha-Stim.

16 DR. EGGERS: Okay. So I've already begged and
17 borrowed from the people who are doing closing remarks
18 to go a few minutes longer, we'll go till 3:25. Again,
19 we -- I mean, we wish this was -- we had more time.
20 It's really important. A summary on the webcast and we
21 can take one phone caller and a phone caller, if you're
22 in line for the phone and you've -- what we've --

1 you've heard your issue discussed, we're going to --
2 please have -- let someone else who has a new issue.
3 Go ahead -- yeah and webcast summary.

4 GRAHAM: It is on now. So on the webcast a
5 lot of people talking about some of the issues that
6 they've run into seeking treatment for themselves.
7 That addiction doesn't show up on a list of topics when
8 they talk to some of their medical professionals. That
9 when they're looking at what they would want in the
10 treatment that it's not necessarily just managing
11 symptoms, like one at a time, like things like craving,
12 but they'd like a more comprehensive solution, other
13 similar sorts of comments like that.

14 DR. EGGERS: Thank you. All right. Before we
15 go to the phone, Mitra wants to ask a follow up
16 question.

17 DR. AHADPOUR: So this is what we were
18 discussing before we went to lunch. I noticed in one
19 of the pollings, the majority of people said they're
20 not concerned for opioid overdose or relapse. Can you
21 just briefly talk about why you are not concerned for
22 an opioid overdose? We are seeing an epidemic of it

1 all across the nation and what are you doing? I mean,
2 is there something -- and I don't want to put any -- my
3 comments, put my ideas into your discussion, but what
4 are you doing that you're not concerned?

5 DR. EGGERS: Okay. First let's get a show of
6 hands. I know it's a tough question. How many of you
7 are concerned about relapse and overdose in your
8 situation? You are concerned. Okay. And how many of
9 you are for whatever reason, you are not concerned
10 about that? Okay, so do have some varying
11 perspectives. Let's hear a couple of comments to
12 answer Mitra's question and then we'll move on to the
13 phone.

14 SHARON: Again, Sharon, I'm not concerned
15 about overdose, because having used drugs as far back
16 as I -- I know there are no -- there's no heroin and I
17 know that what they're selling out here today is
18 everything but, so that's what really got me on a drug
19 withdrawal program, so I don't have any desire to drive
20 what they're selling today, so that's what keeps me
21 away.

22 DR. EGGERS: Okay. One more back there in the

1 red.

2 ANONYMOUS: I would disagree with that because
3 what they're giving out today that's what's previous
4 ordained from, so there's no such thing as non-concern
5 for overdose. We've had more overdose with this thing
6 here that's out than we had when a real one was out.

7 DR. EGGERS: Can I --

8 ANONYMOUS: And we just got a training the
9 other day from these guys right here with the
10 (inaudible) to nose, we just had a training for that.
11 There's no such thing as no overdose, we're not candid
12 about it.

13 DR. EGGERS: Can I ask a follow-up?

14 ANONYMOUS: I mean -- I mean I might be saying
15 it won't, but I want to say that overdose academic is
16 fully out here today. What they're using to date,
17 you're ODing more from that than you would with the
18 real stuff.

19 DR. EGGERS: Thank you very much.

20 ANONYMOUS: Come on now, being -- isn't no
21 joke. It's so --

22 DR. EGGERS: Can I have a show of hand

1 questions? How many of you who expressed some concern
2 about possible relapse and then overdoses, are you
3 carrying the lock-zone (phonetic) Narcan -- are you
4 carrying it on you now? Okay. Okay. Okay, one --
5 okay, thank you for demonstrating. Okay, final
6 comment, then we're going to the phone.

7 ANONYMOUS: We -- be more power. We are very
8 concerned. We're doing our can training in and out --
9 in a city and what we do, we meet people on their own
10 terms wherever they're at, whether they're using or
11 not. We just want you to practice harm reduction. Do
12 not isolate yourself. Do not let anybody take your
13 self-esteem away where you're somewhere isolated in a -
14 - oh, how it's using, an overdose and no one's data
15 help you save your life.

16 DR. EGGERS: Thank you.

17 ANONYMOUS: We are very concerned and we won't
18 stop being concerned.

19 DR. EGGERS: Great. Thanks. Okay. I am
20 going to have to go to the phone, so are there any
21 callers on the phone? Operator, can we have a caller?
22 Again if we don't have, it's just important to allow

1 our webcast participants to be able to chime in a
2 little, but if we don't have any callers, that's fine.

3 SPEAKER: Stanley's line is open.

4 DR. EGGERS: Okay. Okay. We're going to ask
5 you to keep it brief because we're running really short
6 on time, but your comment's important.

7 STANLEY: Okay. Can you hear me now?

8 DR. EGGERS: Yes, thank you.

9 STANLEY: Okay, great. Thanks for the forum
10 to sit in on. My name is Stanley REDACTED. I live in
11 Northwest Ohio and I will make this brief. I'm a 62-
12 year-old husband, father, grandfather, even a great
13 grandfather and a long time business-owner and until 30
14 days ago, I was addicted to opioid pain medication
15 because of an initial 1987 spine surgery. I've had
16 four surgeries since, and 30 days ago -- literally 30
17 years on opioids, until 30 days ago I was treated with
18 Ibogaine hydrochloride. Within 6 hours, it snapped. I
19 have never had another craving, no dope sickness,
20 nothing.

21 Again I'm not a 30-year-old junkie, I am a 62-
22 year-old man who has experienced this and the FDA, I

1 understand you mentioned earlier does not do what the
2 pharmaceutical companies does, put money into research,
3 but somebody should, because this works. I had to
4 travel out of the country to get this done, but
5 Ibogaine saved my life.

6 DR. EGGERS: Great. Thank you. And again we
7 want to hear all experiences with everything that you
8 think is helping you manage your opioid use disorder.
9 Please talk about that through the webcast as we close
10 up or in the docket. We read all the docket comments.

11 STANLEY: Okay. I sure will. I appreciate
12 your time.

13 DR. EGGERS: Thank you. Thank you.

14 STANLEY: But there is no more management. I
15 don't have it anymore thanks to Ibogaine. Thank you.

16 DR. EGGERS: Okay, thank you. Okay. I know
17 there are still hands raised, but if we don't, I'm --
18 I'm worried about these buses that need to head back
19 downtown or back to their places and so we do need to
20 move on, but you are showing that there is still more
21 to the conversation to have. Again, we have the
22 docket. Do we have -- do we put out the website -- the

1 slide for the docket website? This is -- we've touched
2 upon really important issues and we really only got to
3 the surface and we know that -- we knew that that's
4 what we would get. The conversation will continue and
5 I want to thank you all very much for your
6 participation in the meeting today. I think we heard
7 from almost everyone and that is a real measure of
8 success in our book. Can we give a round of applause
9 for the courage --

10 (Applause.)

11 DR. EGGERS: -- and the forthcomingness you
12 had? Okay. So that's the end of the facilitate
13 discussion. Again there are evaluation forms. Please,
14 we really want to know how we've done.

15 OPEN PUBLIC COMMENT

16 DR. EGGERS: We're going to move into the open
17 public comment part and so if you signed up for that,
18 you will hear what we're going to move into there.
19 Thank you very much.

20 DR. WOODWARD: Hi everyone. My name is Shanon
21 Woodward, and right now we're transitioning to the open
22 public comment session of the meeting. So this part of

1 the meeting allows an opportunity for people to comment
2 on topics other than our two main discussion topics.
3 This is also a chance for stakeholders other than
4 individuals and families to speak. Keep in mind that
5 FDA or NIDA will not address comments that we hear
6 during this session, but all the comments are being
7 transcribed and part of the public record.

8 We'd like this to be a transparent process, so
9 we encourage you to note any financial interest that
10 may be relevant to your comment. This also may include
11 things such as travel stipends as well. If you don't
12 have any such interest, you may want to state that for
13 the record. And if you prefer not to provide this
14 information, you can still provide your comment. So we
15 collected signups when the meeting began. Right now,
16 we have 12 speakers signed up. I'm apologizing in
17 advance if I butcher your name. Just correct me, I
18 won't take any offense, and also if I get to your name
19 and you share during the meeting today and you feel
20 that you don't need to provide a comment during this
21 time, just let me know, and I can accommodate you as
22 well.

1 The time for the comments is 2 minutes for
2 each person. We don't have a timer or buzzer, anything
3 like that, so as you get to the end of your time, I may
4 just gently urge you and let you know. So first we
5 have Jack Henningfield. Is Jack Henningfield still in
6 the room? Okay.

7 MR. HENNINGFIELD: Did you say 2 minutes or 10
8 minutes?

9 DR. WOODWARD: Two, two.

10 MR. HENNINGFIELD: I'm Jack Henningfield. I
11 provide consulting through Pinney Associates on
12 addiction, control medicines, pain medicines. I've
13 worked on most of the addiction medicines since
14 methadone. I think I'm proud of that. I think we've
15 come a long way, but listening to people today, we have
16 a lot further to go and I hope you are listening to
17 people today. One of my mentors was former Surgeon
18 General Koop. He was dedicated to making Addiction
19 Science -- Advancing Addiction Science and making
20 treatments as easy it is to get drugs. And we've come
21 a long way, but not nearly far enough. I think he'd be
22 happy with the opioid report from the White House and

1 crushed that it's not being implemented. So what we
2 have is not available to a lot of the people.

3 As you heard today, most people on opioids,
4 it's not just an opioid problem, it's broader mental
5 health problem, it's a societal problem and our
6 treatments have to fit in the context of those
7 problems. There is no one size fits all. We've got to
8 address the needs that people have when they have them
9 with treatments that are acceptable to them and
10 treatments that aren't acceptable, aren't affordable,
11 are no good.

12 I want to make a few comments on Kratom which
13 is used by 3 to 5 million Americans and 4 surveys show
14 that many people are using it as a lifeline away from
15 opioids because it helps with their withdrawal. I
16 think they are telling people that we're going to take
17 it away, it's like telling somebody that's falling into
18 the ocean and struggling with life preservers they were
19 going to take your life preservers away because they're
20 not Coast Guard-approved. That doesn't make any sense.
21 This is a lifeline.

22 And finally the four surveys show that many

1 people who are using Kratom and their families are
2 terrified that FDA and DEA may ban Kratom. What they
3 would like and the surveys show is for FDA to regulate
4 Kratom, help ensure that what they buy is clean and
5 pure and packaged properly. I'll be submitting a
6 longer comment from the record, but I really appreciate
7 what you've done and I really appreciate all the people
8 that have come here today, families and people that
9 have problems, just an incredible eye opener for people
10 like me. I have family members with addiction too, so
11 I can relate to a lot of this at a very personal level.
12 Thank you.

13 (Applause.)

14 DR. WOODWARD: Thank you Jack. We have
15 Richard REDACTED, I know you just shared with us
16 briefly. Next we have Maureen Boyle (phonetic).
17 Maureen Boyle? Okay.

18 MS. BOYLE: So I'm Maureen Boyle. I'm with
19 the Addiction Policy Forum. And I just wanted to first
20 thank FDA for doing this. It's incredibly important.
21 You know, both from the perspective of making sure that
22 we facilitate the development of new medications and

1 facilitate a larger investment in this, but, you know,
2 I think it's also important to remember the message
3 that the abstinence only end-points sends, right, but,
4 you know, if you've managed to cut down by 75 percent
5 that, you know, if you use again, that that's not
6 success, that's failure, right, so instead of
7 celebrating the fact that you were able to stop for
8 that long or cut down to that amount, you're telling
9 people that they failed.

10 And I think that sends a really important and
11 really bad message to patients. And so getting to a
12 place where, you know, other outcomes that are more
13 meaningful to people are an acceptable end-point is
14 really important. And I -- you know, I come from this
15 both as a scientist, as an advocate, but also as a
16 family member. So I have a sister who is in active
17 addiction and has been for decades. And I can tell you
18 that my family does not care what she ingests. Like,
19 we don't care what she's putting into her body. We
20 care about whether she can take care of herself and
21 whether she can hold a job and whether she shows up.
22 And you know, however she can get there, I think is the

1 important thing.

2 And I think if we can look at things like I
3 said other than abstinence, and you know, even if we're
4 looking at like losing the diagnosis, right, like, you
5 know, you talked about before how the diagnosis is made
6 up of compulsion to use and social impacts and physical
7 withdrawal symptoms, so -- but we're not looking at
8 people who, you know, still use occasionally or, you
9 know, still even, you know, if they don't want to and
10 even if they mess up occasionally. But you know,
11 they've managed to reclaim their lives and we don't
12 count that as success, that's insane.

13 (Applause.)

14 DR. WOODWARD: Thank you. Now we have Carol
15 REDACTED.

16 CAROL: Hello. My name is Carol REDACTED and
17 I wanted to just use this period for two issues. One,
18 I came here today to advocate that there's no wrong
19 door to recovery and just because I have taken a
20 particular path which ultimately was absent in space,
21 wasn't always that way, but I kind of feel like that --
22 that there are -- you're put in this box and that

1 somehow if you choose to have abstinence-based
2 recovery, then that means that you're anti people who
3 can manage effective drug use or that you're anti-
4 science or you're anti-MAT, and I think sometimes some
5 of the agencies and others in the field put us in that
6 -- those boxes and try to pit us against one another
7 because it fits their various interest.

8 And I know I am one of many thousands and tens
9 and thousands of people who believe there is no wrong
10 door to recovery and that people get to define their
11 recovery the way that they want to and there is no
12 judgment for many of us. I know the bad actors or
13 people who are loud on social media sometimes get to
14 typecast all of us, but we're good. This is just my
15 pathway. It doesn't mean I judge people who have
16 another pathway. And I think a lot of times at least
17 in policy circles in Washington, which I'm familiar
18 with, somehow, you know, we've gotten shunned as that
19 people who have abstinence-based or bad actors that
20 judge other people and it's just, I've spent my life
21 working to help people recover in any way that they
22 can.

1 The second thing I wanted to talk about was
2 the use of taxpayer dollars to help develop or market
3 or whatever drug abuse-deterrent formulations of
4 medications. I know at least in Congress, you know, a
5 law passed that gives tax credits for the development
6 of drug-deterrent formulations and my personal
7 experience in working with a lot of people in or
8 seeking recovery is that there is a recipe on the
9 Internet to beat every single drug abuse-deterrent
10 formulation. There are people who are clever and smart
11 that have figured out a way to get around all of them.

12 And that continued funding for that instead of
13 putting it into any number of other things, whether
14 it's in a lock-zone or treatment or just education or
15 safe syringe injection sites, whatever, might be a
16 better use of federal policy efforts than drug abuse-
17 deterrent formulations which can be gotten around.

18 Thank you.

19 DR. WOODWARD: Thank you Carol. Next we have
20 Stevenson (phonetic). Is Stevenson --

21 MR. SUN: My name is Steven sun. I'm a
22 physician and vice president and head of Quality Risk

1 Management at Syneos Health. We're an international
2 contract research organization that serves the
3 biopharma company and also serves -- and also has a
4 great interest in serving public health. Thank you for
5 seeking the input of public stakeholders as the
6 development of products for opioid use disorder. And
7 it's part of Syneos Health's commitment to the
8 improvement of public health.

9 And a 2017 research collaboration agreement of
10 a risk repository system with the FDA for providing a
11 systematic risk assessment of a multi-stakeholder
12 journey for opioid use disorder as is demonstration of
13 the system's risk repository capability which we've
14 deposited in the FDA docket for public read and share
15 to intend for such analysis to provide decision-makers
16 and governing industry an efficient platform for
17 understanding complex issues that involve a multitude
18 of stakeholders that could be achieved through the
19 systematic mapping of each stakeholder's perspective.

20 And in this case for opioid use disorder, we
21 acknowledged the numerous questions that are asked
22 specifically from the patient's perspective and we made

1 an attempt to highlight the patient journey in the
2 broader perspective that details of the stakeholder as
3 well as others associated with OUD.

4 As a former medical officer of the U.S. FDA
5 seeders division risk management controlled substances,
6 I experienced repeated challenges to access experts on
7 the short timelines for evaluating products as part of
8 developing a comprehensive risk assessment. And from
9 this need, a framework emerged to develop a continuous
10 learning system so that each unique bolus of new
11 information and lessons learned could be additive and
12 compound to a growing and intelligent knowledge-base.
13 And we do believe many stakeholders lack the access to
14 see each other's perspectives.

15 So multi-stakeholder risk assessment would be
16 a cooperative solution to help support many
17 stakeholders including patients, providers, government
18 associates in the industry who are also likely
19 developing from scratch very similar or overlapping
20 risk assessments. We're also advancing this expansion
21 to include an engineering-grade failure mode and
22 effects analysis for common share. Thank you for the

1 time.

2 DR. WOODWARD: Thank you Steven. Now we have
3 Kevin REDACTED.

4 KEVIN: So I wanted to just bring up two
5 points, first their kind of preface I thought I saw in
6 the slide from one of the representatives from NIDA
7 quote about drug abuse being taking a substance that
8 changes mood or mind-altering effects and that struck
9 me as a little odd. I think all of us as human beings
10 inherently want to experience a range of states of
11 consciousness. Otherwise we wouldn't fall asleep and
12 dream.

13 The other thing I heard a very consistent
14 theme about people developing an opioid use disorder
15 from a legitimate prescription during a medical
16 procedure. I kind of want to draw attention to some
17 data that wasn't reflected. I don't want to deny
18 anybody's experience, but that tends to be the
19 exception and not the norm, most people who get
20 prescribed opioids for chronic pain do not become
21 addicted, but again that's not to deny anybody's
22 experience who spoke today.

1 The second thing I want to say is that as
2 healthcare providers, as scientists, as advocates, as
3 individuals and families, I would love if we could all
4 agree that the criminal justice component of this issue
5 needs to be removed completely.

6 (Applause.)

7 KEVIN: If I drive under the influence of a
8 substance and a policeman pulls me over, I deserve to
9 be prosecuted to the fullest extent of the law, but if
10 I am "exhibiting drug-seeking behavior", sorry, I'm
11 exhibiting the characteristic of a person with an
12 opioid use disorder, I would prefer if I can walk into
13 a hospital and get a measured dose of Oxycodone, then I
14 could have a fentanyl-soaked bag of (expletive) that I
15 had to get from my dealer in Brooklyn every other day.

16 So this is just the plug to end the drug war,
17 vote for a formal end to district attorneys. If any
18 sheriffs refused to equip their officers with Narcan,
19 vote them out of office. This is not a moral failing.
20 It's a learning disorder. We could catch it early with
21 people -- with young people that are exhibiting effects
22 of trauma, effects lacking resources and family

1 support, we could intervene on these people early
2 enough that we could perhaps save them from this
3 affliction. Thank you.

4 DR. WOODWARD: Thank you Kevin. Now we have
5 Juliana REDACTED.

6 JULIANA: Hi, I just want to first say that I
7 don't want to disqualify anybody's personal experience
8 to my opinion. I believe that there is a million --
9 more than a million different paths toward recovery or
10 whatever you want to call it, and different things work
11 for different people, but in my personal experience, I
12 found the use of the disease concept of addiction very
13 unhelpful. I do not believe that it is a disease. It
14 actually does not fit the definition of a disease.
15 It's a not a science-based definition, and I stopped
16 using opioids 6-1/2 years ago with Ibogaine.

17 I don't consider myself an addict, I do not
18 have a disease, and I don't consider myself powerless.
19 I feel that the disease concept of addiction eliminates
20 possibility for the exploration of the many unique
21 experiences, emotional conditions that every person
22 has. It's like a blanket statement saying you have a

1 disease, and it does not leave room for investigating
2 the many different diverse paths that lead a person to
3 use substances. So I would just like to advocate for
4 transition away from that concept, and the embracing of
5 the fact that everybody suffers in some way. The fact
6 that I chose to deal with it with a substance doesn't
7 make me different from a person that chooses to deal
8 with it through shopping, or through television, or
9 through gambling. We all suffer in different ways and
10 find different ways to deal with it.

11 For some reason, substance users have been
12 designated as this other population. Why is it that
13 when you use a substance to deal with a difficult
14 emotional situation, that's different than dealing with
15 a difficult emotional situation in a socially
16 acceptable way? I think that that's bullshit. I also
17 just want to go on to say that since using Ibogaine 6-
18 1/2 years ago, I do not have opioid cravings. I am not
19 at risk for relapse, that is not even a possibility in
20 my horizon.

21 After doing Ibogaine, I stepped out of that
22 life, and I am no longer in the realm of risk and I do

1 not consider myself at risk for any of these things
2 that we have been talking about. I'm not saying that's
3 what's going to happen to anyone that uses Ibogaine,
4 but the fact that that's happened for me and this
5 person that called in and many other people that I have
6 help treat with Ibogaine, that is significant. It is a
7 huge deal that this is the only drug that gets rid off
8 -- that attenuates opioid --

9 DR. WOODWARD: Thank you Juliana. Any final
10 thoughts?

11 JULIANA: I have a final thing to say. I just
12 -- we really want to talk about helping people, we need
13 to talk about total decriminalization of drugs because
14 that is the one thing that would immediately save
15 thousands, if not millions of lives right now.

16 DR. WOODWARD: Thank you Juliana.

17 (Applause.)

18 DR. WOODWARD: Our next speaker is Shilo

19 REDACTED

20 SHILO: Hi, I have a little list, I'm sorry.
21 I am a 42-year-old lifelong drug user who -- I'm the
22 founder of the Urban Survivors Union and I don't get a

1 lot of chance to talk to the FDA, so one of things I
2 want to talk about is Naloxone. You keep -- you --
3 recently, you just led a auto injector through that's
4 \$1,000. We are just trying to get Narcan in people's
5 hands. It's unhelpful to keep reinventing the wheel to
6 make drugs more costly than it is to just getting more
7 generics out there for like liquid-based or injectable
8 Naloxone. The other thing I want to talk about is with
9 Medicaid-assisted treatment for opioids, we have
10 nothing for stimulants.

11 We don't have anything for methamphetamine, we
12 don't have anything for cocaine, and in the West Coast,
13 more people use stimulants than use opioids, and we
14 still have no plan for treatment for them. The only
15 thing that I've ever seen is people prescribing anti-
16 depressants a month before they're considering stopping
17 which is very unhelpful and hard to gauge. The other
18 thing is it's really important that we get better
19 control and quality for Kratom, and we do not make it
20 illegal, and we do not make it hard to get. People --
21 thousands of people are being forced to use Kratom
22 because we've made methadone clinics so inaccessible,

1 we've made Suboxone clinics so inaccessible. To be
2 perfectly honest, I think the DEA does more harm to
3 getting treatment in people's hands than it does
4 helping them.

5 I also think stigma -- I think we really need
6 to get away from this idea of bad drug users, good drug
7 users because to be perfectly honest, I've used drugs
8 my whole life and the only drug that has been the most
9 detrimental to my body has been sugar and it's the only
10 one that people have always commented. That's why I
11 have a round belly. And so --

12 DR. WOODWARD: Thank you Shilo. And if any
13 final comments, final thoughts?

14 SHILO: Yes, I think it's really important
15 that we start doing more research for Ibogaine. I
16 think it's very successful, and we've seen large
17 amounts of success in Seattle using it, and I think we
18 -- and also we need to do more research for
19 methamphetamine in general.

20 (Applause.)

21 DR. WOODWARD: Thank you. I'm going to turn
22 over to our next speaker Reginald REDACTED. Also in

1 terms of timing, I just want to do a quick time-check,
2 let everyone know we're getting close to the 3:45 mark,
3 so if you need to be on one of those buses, we don't
4 mind if you have to step out.

5 REGINALD: Thank you very much. I don't. I'm
6 aware of this meeting being to develop something for
7 opioids, but as a drug user myself, not even as an
8 opioid drug user, I recognize the end-point should be
9 the goal, right? I'm from the other Washington. While
10 opioid use there is, as it is throughout the nation,
11 again the end-point focus should be shifted so the
12 criminalization of it is removed. If I wanted to use
13 whatever drug, decriminalizing and making available
14 alternative medication to manage, you know, anyone's
15 drug use with the end-point being happier, healthier
16 drug use if used. Try that as the end-point of
17 patient-focused drug development. Thank you.

18 (Applause.)

19 DR. WOODWARD: Thank you, Reginald. Now we
20 have Alice REDACTED. Alice REDACTED? Okay. Next we
21 have Dennis REDACTED. Dennis REDACTED. She's still --
22 okay.

1 DENNIS: So I had an opportunity to interact
2 this morning and I thank you for that. So I'll make it
3 real brief. I think I was able to talk about the
4 family caregiver piece a lot. There's many of us,
5 millions out here, so I want to preface this saying
6 it's not about me, but what the landscape looks like
7 for millions of us is finding out your child is sick
8 and having no support systems, being denied treatment
9 for 2, 3 years with insurance, with private insurance,
10 with employer insurance, having no real good resources
11 that empower that parent to be part of that recovery or
12 wellness toolkit and oftentimes, you know, just
13 financial room.

14 My son's in recovery, and I think of all the
15 above, and I know that I'm one of the lucky ones, but I
16 know that the 30 e-mails I get today from -- on social
17 media, I know that the hundreds of calls we get at the
18 partnership for peer supports, there is a lot of people
19 that look just like me still on this journey.

20 So part of when we were discussing things
21 today, I think of the medication -- treatment side of
22 it, right, so not were we just denied treatment, were

1 denied treatment medications, we're denied everything.
2 So I think that's a real big hurdle for us, and I don'
3 know what that looks like to help people that are
4 denied. The other thing is, is that I think that
5 consumer-faced education is really important.

6 Again, when you have lack of resources in
7 education to know that our son -- you know, we paid
8 \$700 a week and that's fine for Suboxone, but to know
9 that he was giving him Xanax at the same time, early on
10 in the journey, I don't know that that's paid off. I'm
11 just happy that maybe he's not craving, so that
12 consumer-facing education is really important,
13 especially for families.

14 And I also think what Carol (phonetic) said,
15 just other means, so whether it's that app that
16 supports you, that consumer-face application and really
17 just not -- just the script, right, because when we
18 learned about medication-assisted treatment, we heard a
19 whole lot about continuum supports, right, and getting
20 them healthy and well and that individual recovery
21 because it's so much more than substances. So we don't
22 see that. So a lot of questions were asked today like

1 would you like that pill. I think we all would, but we
2 would like the support system surrounding it as well.
3 I think it's really important for that wellness piece
4 of it. So thank you.

5 DR. WOODWARD: Thank you Denise. Next we have
6 Megan Polanin. Megan Polanin?

7 DR. POLANIN: Thank you. My name is Dr. Megan
8 Polanin from the National Center for Health Research.
9 Our center analyses scientific and medical data,
10 promotes consumer-oriented health policy and
11 legislation, and focuses on patient-centered research
12 and treatment. We do not accept funding from industry,
13 so I have no conflicts of interest to report. We thank
14 the FDA and NIDA for convening today's meeting to
15 elevate patient stories. It's critical to know
16 patient's perspectives on opioid use disorder and this
17 meeting is a positive step at initiating a productive
18 dialogue. We know that the FDA has made a commitment
19 to finding ways to reduce opioid use and addiction
20 including improving more treatments for opioid use
21 disorder.

22 We also know that drug companies are eager to

1 get patients who want more treatments to talk with FDA
2 officials. Kaiser Health News recently published their
3 prescription for Power database and reported that in
4 2015, pharmaceutical companies gave at least \$116
5 million to patient advocacy groups. We want the FDA to
6 hear from patients and are concerned that they're not
7 hearing perspectives that represent the wide range of
8 patients and their loved ones affected by opioid use
9 disorder. Patients who aren't involved with these form
10 of funded patient groups may not know how to engage
11 with the FDA.

12 If they know about public meetings like this
13 one, they may not have the means to attend and many
14 don't know about opportunities to send written public
15 comments to the FDA docket. Patients often ask as if
16 it's worth their time and expense to come to an FDA
17 meeting when they're given only a few minutes to speak
18 and can only register to speak the morning of the
19 meeting. We've heard from patients that they don't
20 want to come to the FDA meeting at their own expense
21 without a guarantee that they will have a chance to
22 speak and be heard.

1 DR. WOODWARD: Thank you. Any final thoughts?

2 DR. POLANIN: Yes. So to ensure that the
3 patient perspective is well represented, the patient
4 engagement process should be inclusive and transparent,
5 and we would encourage the FDA to continue to do so and
6 make even more efforts. So thank you to the patients
7 who've shared their stories today, and we appreciate
8 the opportunity to express our views.

9 DR. WOODWARD: Thank you.

10 DR. POLANIN: Thank you.

11 DR. WOODWARD: I'll now be turning it over to
12 one of my colleagues for some closing remarks and also
13 just for a time-check, it's 3:53, if you are taking one
14 of the shuttles back.

15 CLOSING REMARKS

16 DR. AHADPOUR: We just wanted to briefly take
17 this opportunity to thank all of you for those who
18 came, some came long distances and anyone who joined us
19 virtually. You shared your stories, we have listened
20 and we have learned a great deal, so we are grateful
21 for it.

22 I also wanted to thank all the individuals who

1 were involved in the planning, the panelists from FDA;
2 NIDA; Office of Center Director; control substance
3 staff and PACE Office of Communications (phonetic);
4 Office of Media Affairs; Office of Minority Health;
5 Office of New Drugs; Division of Anesthesia, Analgesia
6 and Addiction products and Clinical Outcome Assessment
7 Staff; Office of Strategic Programs; senior FDA
8 leadership and/or NIDA colleagues and advocacy and
9 support groups.

10 I really wanted to just really end it by
11 saying thank you, a big thank you, and also just to
12 mention that opioid uses, so there is a chronic
13 illness, it is treatable. There is evidence-based
14 treatment, and I just wanted to give the -- there was a
15 lot of discussions about trauma, mental illness and
16 addiction. There is treatment available. The SAMHSA
17 treatment locator is one good place to go to find a
18 treatment that is close to you, and I also wanted to
19 give the number for the suicide prevention hotline, 1-
20 800-273-8255. So thank you so much and safe trip back
21 home.

22 (Applause.)

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CERTIFICATE OF NOTARY PUBLIC

I, SAMUEL HONIG, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this actio



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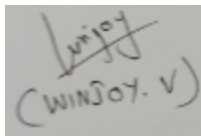
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CERTIFICATE OF TRANSCRIBER

I, WINJOY VIJAYAN, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

April 30, 2018

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Winjoy' with '(WINJOY.V)' written below it.

Date

WINJOY VIJAYAN

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